85-1567

Supreme Court, U.S.
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No.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

FRANK E. BUSH, INC.,

Petitioner,

v.

THE UNITED STATES POSTAL SERVICE,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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QUESTIONS PRESENTED

1. When the existence of a scientific controversy is established by a user of the mails, may the Postal Service assume the existence of a scientific consensus to justify imposition of a mail stop order?

2. Where a stop order is justified, does the First Amendment require that it be narrowly drawn?

All parties to the proceeding in the Court below are listed in the caption. Frank E. Bush, Inc. is a New York Corporation that has no parent or subsidiaries.

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PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

OPINIONS BELOW

All of the opinions below are unreported. The unpublished order of the Court of Appeals for the Second Circuit is printed in the Appendix ("App.") at pp. A-1 to A-3, as are the District Court's memorandum endorsement (pp. A-5 to A-6) and the Magistrate's report and recommendation (pp. A-7 to A-18).

JURISDICTION

The opinion and judgment of the United States Court of Appeals for the Second Circuit were issued on October 30, 1985. Justice Marshall entered an order on January 23, 1986, extending the time within which to file this petition until February 15, 1986. This Court's jurisdiction is invoked pursuant to 28 U.S.C. § 1254(1). The jurisdiction of the United States District Court for the Southern District of New York was invoked pursuant to 28 U.S.C. §§ 1331 and 1339, 5 U.S.C. § 703, and 39 U.S.C. § 409.

STATUTE AND REGULATION INVOLVED

Section 3005 of Title 39 of the United States Code provides, in pertinent part:

> (a) Upon evidence satisfactory to the Postal Service that any person is engaged in conducting a scheme or device for obtaining money or property through the mail by means of false representations, including the mailing of matter which is nonmailable under section 3001(d) of this title, or is engaged in conducting a lottery, gift enterprise, or scheme for the distribution of money or of real or personal property, by lottery, chance, or drawing of any kind, the Postal Service may issue an order which —
>
> > (1) directs the postmaster of the post office at which mail arrives, addressed to such a person or to his representative, to return such mail to the sender appropriately marked as in violation of this section, if the person, or his representative, is first notified and given reasonable opportunity to be present at the receiving post office to survey the mail before the postmaster returns the mail to the sender; . . .

The United States Postal Service has adopted Rules of Practice in Proceedings Relative to False Representation and Lottery Orders, which appear as Part 952 of Title 39 of the Code of Federal Regulations.

STATEMENT

Petitioner distributed NSP-270, a vitamin-mineral tablet, the principal ingredient of which is zinc. To promote sales of NSP-270, petitioner mailed advertising which called attention to recent scientific studies demonstrating the necessity of zinc for male sexual performance and the role of inadequate zinc consumption in development of sexual deficiencies.

On December 22, 1982, the United States Postal Service ("Postal Service") filed a complaint, pursuant to 39 U.S.C. § 3005, against petitioner, alleging that petitioner's advertising contained eleven misrepresentations. After a hearing, the Postal Service Administrative Law Judge ("ALJ") issued the Postal Service's Initial Decision on January 27, 1984, which found that petitioner had made all of the representations alleged in the complaint and that all were false. Petitioner excepted to that decision and sought review within the Postal Service. On October 10, 1984, the Postal Service Acting Judicial Officer ("Judicial Officer") issued the final Postal Service Decision, which essentially affirmed the ALJ's Initial Decision in all respects. Pursuant to his final Decision, the Judicial Officer then issued Order No. 84-93 (App., at pp. A-19 to A-20) (commonly called a "stop order"), which directed postmasters at postal stations receiving mail addressed to petitioner to return it to the sender after marking it with an indication that an order had issued against petitioner for violation of the false representation law.

On December 6, 1984, petitioner filed a complaint in the United States District Court for the Southern District of New York, seeking injunctive and declaratory relief, alleging that the proceedings before the Postal Service had been tainted by reliance on evidence not in the record and by misallocation of the burden of proof, that the Postal Service's findings were not supported by substantial evidence, and that the stop order impermissibly infringed upon petitioner's rights under the First Amendment. After referral to her, the Magistrate issued, on May 15, 1985, a report and recommendation to deny petitioner the relief sought.

By memorandum endorsement dated May 29, 1985, the District Court adopted and approved the report and recommendation. Petitioner thereupon appealed to the United States Court of Appeals for the Second Circuit, which, on October 30, 1985, affirmed the judgment below. This appeal followed.

REASONS FOR GRANTING THE WRIT

I. THE POSTAL SERVICE'S PRESUMPTION OF A SCIENTIFIC CONSENSUS IN AREAS WHERE SCIENTIFIC DEBATE IS ONGOING IS IMPERMISSIBLE IN § 3005 PROCEEDINGS.

In its final Decision, the Postal Service conceded that "zinc is a critical nutrient for sexual development and abilities," and that the average man "ingests less zinc than the Recommended Dietary Allowance (RDA) of 15 mg. per day" but nonetheless found that "those facts do not *establish the truth* of the representations in question" (App., at p. A-27). Notwithstanding these critical concessions, petitioner can use the mails to express these facts only at its peril. The Postal Service, shielded from effective judicial review, has failed to heed this Court's warning that, where scientific issues are involved, and "where knowledge has not yet been crystallized in the crucible of experience,"[1] ideas are still in the "opinion" stage and "afford[] no basis for a fact determination as to whether a false representation has been made." *Gottlieb v. Schaffer*, 141 F.Supp. 7, 18 (S.D.N.Y. 1956).

What the Postal Service has done, in this case and others, is to condemn new ideas simply because they differ from those it advances. After branding ideas or statements "false," the Postal Service assumes that all First Amendment questions are foreclosed. This case presents one of those in which the Postal Service seeks to establish the existence of a "consensus" of medical opinion where there is none, and then finds guilty of making

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[1] *Reilly v. Pinkus*, 338 U.S. 269, 274 (1949); *see also American School of Magnetic Healing v. McAnnulty*, 187 U.S. 94 (1902).

misrepresentations anyone who promotes an idea not in accord with that "consensus."[2]

The procedures by which petitioner's mail was stopped were skewed from the beginning to permit the Postal Service to enforce its own version of orthodoxy in an area of science which is still in an experimental — and, therefore, "opinion" — stage. It is not surprising that in the kind of case presented here the Postal Service awards itself a stop order on *every* complaint it brings. S. Rep. No. 51, 98th Cong., 1st Sess. 155 (1983). Through the procedures created by the Postal Service, and permitted by the courts, any minority scientific opinion is automatically found to be a false representation.[3]

Moreover, the finding of a consensus contradicting facts contained in petitioner's advertising was based on incompetent "evidence"; for example, the Postal Service treated as a "fact," and relied on, a non-medical doctor's "prediction" that the RDA of zinc would "soon" be lowered. (App., at p. A-6)[4] A "consensus"

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[2] It is important to note in this case that the Postal Service has never claimed that any potential harm is associated with the use of petitioner's product. There has never been any suggestion that NSP-270 is anything other than a beneficial vitamin-mineral supplement, nor does this case involve a product whose consumers might fail to obtain some other, conceivably more effective, treatment.

[3] Indeed, in this case petitioner argued that the opinion expressed concerning the potential beneficial effects of zinc on men's sexual development is the majority view, which was established through the testimony of two medical doctors and hundreds of pages of medical studies. It was only the improper reliance on material not in evidence, and not subject to cross-examination, which permitted the Postal Service to claim that its finding of falsity was the "consensus" view. Contrary to the Court of Appeals' finding that the error was "harmless" (App., at p. A-2, ¶3), this Court has held that such a failure to permit effective cross-examination of a Postal Service's expert witness is not harmless. *Reilly*, 338 U.S. at 275-76.

[4] The "prediction" was apparently made, and relied upon as "fact," to overcome the truth of petitioner's representations that a large percentage of the population receives less than the RDA of zinc. This "prediction" was made in 1983; the prediction has irrefutably been proven wrong by the National Academy of Science's recent refusal to lower the RDA for zinc.

contrary to petitioner's representations was also found by the Postal Service when it found that, although two out of three medical studies supported petitioner, the question "is 'still up in the air' " and, therefore, petitioner's representations were false. (App., at p. A-58) This is a classic "heads I win, tails you lose" situation for petitioner, or anyone else who promotes ideas or products the Postal Service does not like. The Postal Service's reliance on its own hypothetical consensus when there is none is simply its way of insuring that views other than those it specifically espouses are labelled "false" and are thereby stopped.

The statement by an expert to a subcommittee considering the 1983 amendments is instructive:

> Today's truths and today's informed opinion are often tomorrow's quaint and sometimes amusing and sometimes not so amusing false ideas. At one time the consensus of informed medical and scientific opinion held that bleeding people with leeches was healthy.
>
> * * *
>
> Under the first amendment, there is no such thing as a false idea. Although the Postal Service may not intend it, the direct result of its actions is the suppression of ideas.

Hearings on H.R. 3973 Before the Subcomm. on Postal Personnel and Modernization of the House Committee on Post Office and Civil Service, 97th Cong., 2d Sess. 59 (1982). Scientific understanding of the physiological significance of zinc has not yet been "crystallized in the crucible of experience" but there has been, and continues to be, scientific study of the issues. Man's need for zinc was not recognized until very recently; the first RDA for zinc was established in 1974. Much of the current scientific literature on the need for zinc focuses on its effects on man's sexual development, on testosterone and on sperm count and motility. While the Postal Service may not like petitioner's advertising, it could not have been stopped but for the free rein given

the Postal Service by the courts, which refuse to scrutinize the manner in which it resolves all ongoing scientific disputes in its favor. The Postal Service was never intended to be the arbiter of scientific debate; but until the courts reject the sweeping stop orders it issues, the Postal Service will have the last word in any controversy involving scientific questions it chooses to determine.

An example of how the Postal Service ensures its victory in these cases is its placement of the burden of proof on the respondent in Postal Service proceedings. This misallocation of the burden of proof is not necessarily done explicitly, but it clearly enough is done. Thus, in the Postal Service Decision here, the Judicial Officer, while acknowledging that the Postal Service had the burden of proving the falsity of representations, repeatedly evaluated the evidence in light of whether petitioner proved the truth of representations or the efficacy of its product. The Postal Service Decision is replete with references displaying the erroneous allocation of the burden of proof:

(a) "*to prove the truth of these representations, [petitioner] relies* on two facts which are essentially undisputed" (App., at p. A-27) (emphasis supplied);

(b) "*not establish[ing] the truth of the representations* in question" (App., at p. A-27) (emphasis supplied);

(c) "*not tend[ing] to prove the truth of [petitioner's] representations*" (App., at p. A-31) (emphasis supplied);

(d) "*fail[ing] to prove the efficacy* of [petitioner's] product" (App., at p. A-33) (emphasis supplied);

(e) "*fail[ing] to prove the efficacy* of oral zinc products such as NSP-270" (App., at p. A-33) (emphasis supplied);

(f) "*fail[ing] to establish the efficacy* of NSP-270" (App., at p. A-33) (emphasis supplied);

> (g) "while the zinc in [petitioner's] product can reverse some zinc deficiencies, it has not been shown that small organ size or poor sexual performance in males is attributable to zinc deficiency" (App., at p. A-37).

The Court of Appeals similarly misplaced the burden.

> Both the Administrative Law Judge (ALJ) and the Postal Service Judicial Officer properly required the government to bear the initial burden of proof to support its claim of false representation; *thereafter the burden shifted to the appellant to come forward with affirmative evidence of truthfulness.* See *Texas Dep't of Community Affairs v. Burdine*, 450 U.S. 248 (1981).

(App., at p. A-2, ¶1) (emphasis supplied). The Court's analysis is in error. First, not all of the representations alleged by the Postal Service to have been made were in fact made. Thus, petitioner was required to "come forward with affirmative evidence of truthfulness" of representations it did not make. Second, assessing the "truthfulness" of conflicting scientific studies is not within the competence of the Postal Service. The ALJ heard the testimony of four experts, two medical doctor witnesses for petitioner, one medical doctor and one Ph.D. for the Postal Service. The testimony and documentary evidence — consisting of hundreds of pages of medical studies — at a minimum showed that no "consensus" yet exists as to the effects of zinc on men's sexual development and abilities.

The numerous studies in evidence did show that zinc had a definite effect on impotence and on testosterone and sperm levels. The only competent record evidence also showed that failure to receive adequate dietary zinc is a problem for many individuals of all income levels, and especially the elderly. Petitioner should not be denied use of the mails for these statements because the Postal Service claims that a "consensus" of falsity was established. This "consensus" was established through the Postal Service's witnesses' responses on direct examination that they "believed"

that their "testimony" was "consistent with the consensus of informed medical opinion." Cross-examination and documentary evidence showed that no "consensus" exists. The outcome in this case has been typical of those in which Postal Service findings have been reviewed with extreme deference: courts sustain the findings of falsity, on such slender reeds, permitting the Postal Service to stop in their tracks any views it finds distasteful.

As another witness told the subcommittee, "it appears that the Post Office has taken up the sword for the medical establishment":

> The Postal Office uses its already overbroad authority to suppress various products. A prime victim of this sort of action is the entire holistic health field. Under Postal Service created precedents and case law, the Post Office has reached the point where it has stretched its already broad authority like taffy to the point where it has decided that if a product, or what you say about it, is not in consensus with the majority of informed medical and scientific opinion, then that product is false and misleading.

S. Rep. No. 51, 98th Cong., 1st Sess. 147 (1983). As this Court held in *Reilly*, the "power to condemn new ideas as fraudulent solely because some cling to traditional opinions with unquestioning tenacity," 339 U.S. at 274, should be carefully checked. The Postal Service, through the application of its rules and procedures, has boldly refused to be bound by this Court's rulings.

II. THE EXCESSIVELY BROAD STOP ORDER HERE INFRINGES PETITIONER'S FIRST AMENDMENT RIGHTS.

The Court ofl Appeals approved the Postal Service's position that its stop order raises no constitutional problems. In doing so, the Court relied on the assumption that petitioner's advertisements were commercial misrepresentations entitled to no First Amendment protection (App., at p. A-2, ¶ 4). The Court's reliance on that assumption ignored a critical aspect of petitioner's objection to the stop order — that the order prevents petitioner from

running advertising based on representations that the Postal Service has never alleged to be false or has even conceded to be truthful.

On its face, the stop order is limited only by its reference to the "sale of NSP-270." Nothing in the order identifies what misrepresentations petitioner is alleged to have made. Thus, there is no practical way for petitioner to inform a postmaster that advertising issued in the future does not contain the alleged misrepresentations involved here and that responses to that advertising should, therefore, not be stopped. In defending its order in the Court of Appeals the Postal Service claimed for the first time that the order would be applicable only to attempts to sell NSP-270 on the basis of the eleven misrepresentations set forth in the Postal Service's complaint. Yet the facially obvious purport of the order is to bar petitioner from selling NSP-270 at all, whether on the basis of false representations, true representations, or no representations.[5]

The Postal Service's cavalier attitude toward the sweep of its order and the relationship of that order to the process that gave rise to it is highlighted by the inclusion within the order's prohibition of representations that the Postal Service has not even tried to prove false or has conceded to be true.

For example, the Postal Service initially charged petitioner with making, *inter alia*, the false representation that: "(i) Tests conducted by the USDA at Beltsville, Maryland on its own employees revealed that 2 out of 3 were significantly short of the recommended levels of the 'sex nutrient' [*i.e.*, zinc] contained in NSP-270." (App., at p. A-48) In his Initial Decision for the Postal Service, the ALJ — who had heard testimony from one of the Postal Service's witnesses that the quoted representation was "very true" — recognized that there was no misrepresentation: "The Beltsville experiment. . . found that the subjects' average intake

[5] The stop order on its face seeks to interfere with "no representation" sales of NSP-270 such as fulfillment of the numerous reorders received by petitioner, reorders based entirely on consumer satisfaction.

of zinc was 8.6 mg. per day [,which] is below the RDA for zinc of 15 mg. per day . . . ." (App., at p. A-55) Nonetheless, he concluded that representation (i) was false because, in his view, that representation gave rise to an implication — "that the subjects of the Beltsville study were *sexually deficient*" (App., at p. A-55) (emphasis supplied) — and that *implication* was false.

In the final Postal Service Decision, the Judicial Officer agreed with the ALJ's conclusion that representation (i) was false, but the Judicial Officer based his conclusion on the finding that the representation "g[a]ve the impression that the USDA study found that two out of three subjects had a *significant zinc deficiency*." (App., at p. A-34) (emphasis supplied) Upon petitioner's federal court challenge to the stop order, the Magistrate, in her report and recommendation, ratified the ALJ's decision that the representation itself was false because a false implication (albeit one different from the one the ALJ had relied on, or the one the Judicial Officer had mentioned), could be derived from it (App., at p. A-15).

Under the Postal Service rules governing proceedings pursuant to 39 U.S.C. § 3005, a stop order is incorporated in the record of the proceeding giving rise to it (39 C.F.R. § 952.28(a)). Thus, the stop order here was issued pursuant to a finding that petitioner had made eleven misrepresentations, representation (i) among them. That finding should govern the stop order, limiting its application to such misrepresentations as were actually alleged. Yet the order contains no such limitation. The order purports to prevent petitioner from selling NSP-270 at all, even if the representations used are ones never reviewed by the Postal Service or even if the sole representation used is one conceded by the ALJ, the Judicial Officer, and the Magistrate to be literally true.

Neither the Court of Appeals nor the District Court faced the difficulty inherent in this procedure. The findings and conclusions of the Postal Service prevent petitioner from using any new and truthful representations in advertising NSP-270, from using

the concededly truthful representation (i), even from knowing what implication or impression the Postal Service might choose to derive from some other truthful representation. The complete absence of detail in the stop order makes it impossible for petitioner to determine what representations are not covered.

Against that background, the stop order manifestly goes further than is constitutionally justifiable in restricting petitioner's ability to advertise its product truthfully. The Postal Service's need to suppress allegedly false representations cannot excuse the excessive sweep of its order here. This Court has instructed that: "Commercial speech that is not false or deceptive and does not concern unlawful activities, however, may be restricted only in the service of a substantial government interest, and only through means that directly advance that interest." *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. __, __, 105 S.Ct. 2265, 2275, 85 L.Ed.2d 652, 664 (1985). The "complete suppression" of proposed advertising is inappropriate "[i]n the absence of a showing that more limited speech regulation would be ineffective . . . ." *Central Hudson Gas & Electric Corporation v. Public Service Commission of New York*, 447 U.S. 557, 571 (1980). In short, "restrictions upon [potentially misleading] advertising may be no broader than reasonably necessary to prevent the deception." *In re R.M.J.*, 455 U.S. 191, 203 (1982).

In other cases, the federal courts have agreed on the significance of those principles in reviewing agency attempts to restrict allegedly deceptive advertising. "[A]ny governmental agency[] must start from the premise that any prior restraint is suspect, and that a remedy, even for deceptive advertising, can go no further than is necessary for the elimination of the deception." *Beneficial Corporation v. F.T.C.*, 542 F.2d 611, 620 (3d Cir. 1976), cert. denied, 430 U.S. 983 (1977). In *Beneficial Corporation*, the Court of Appeals observed that "where qualifying explanatory language does not inherently contradict the advertiser's identifying language it should be accepted in preference to requiring excision," citing *Elliot Knitwear, Inc. v. F.T.C.*, 266 F.2d 787, 790 (2d Cir. 1959), and concluded

that the F.T.C. had exceeded constitutional limits on its authority where it "fail[ed] to consider fully the feasibility of requiring merely that advertising copy be rewritten in lieu of total excision of the offending language," *Beneficial Corporation*, 542 F.2d at 619.[8]

Similarly, the Court of Appeals refused to approve the overly broad remedy sought by the agency in *F.T.C. v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35 (D.C. Cir. 1985). In that case, a cigarette manufacturer had been found to have misrepresented the tar content of a brand it marketed when it used in its advertisements a measure of tar content different from that used by the F.T.C. and the rest of the industry. The Court of Appeals affirmed the finding that the tobacco company's advertising was misleading but ruled that an injunction simply prohibiting such advertising was too broad, since the deception could have been remedied by the inclusion in the company's advertising of measurements of tar content for competing cigarettes according to the company's distinctive measuring method. *Id.* at 44-45.

The decision of the Court of Appeals in the present case is clearly inconsistent with First Amendment principles as applied to commercial representations. Taken together with the record of the proceeding in which it is incorporated, the stop order

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[8] The Postal Service's presumption of what "impression [the advertising] would most probably create in ordinary minds[,] *Donaldson v. Read Magazine*, 333 U.S. 178 (1948)," (App., at p. A-62) misses the point. In the years since *Donaldson*, this Court has rejected the notion that incomplete but accurate information may be suppressed as misleading, since that notion is based on the impermissible assumption that "the public is not sophisticated enough to realize the limitations of advertising, and that the public is better kept in ignorance than trusted with correct but incomplete information." *Bates v. State Bar of Arizona*, 433 U.S. 350, 374-75 (1977); *see also Bolger v. Youngs Drug Products Corp.*, 430 U.S. 60 (1983). The Postal Service, assuming that the public is too unsophisticated to understand advertising, has determined that a complete halt is preferable to a required modification and that the public should be kept in ignorance rather than permitted to make its own informed decision.

is not narrowly drawn. On the contrary, exactly like the injunction modified by the Court of Appeals in *F.T.C. v. Brown & Williamson Corp.*, this stop order prevents petitioner from using a truthful statement in its advertising and is excessively broad in "failing to consider fully the feasibility of requiring merely that advertising copy be rewritten," *Beneficial Corporation*, 542 F.2d at 619. The Court of Appeals decision approving the stop order conflicts with this Court's analysis of the constitutionally acceptable limitations on commercial speech and clashes with decisions by other federal courts applying that analysis.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

At a stated Term of the United States Court of Appeals for the Second Circuit, held at the United States Courthouse in the City of New York, on the 30th day of October one thousand nine hundred and eighty-five

Present:

HON. LAWRENCE W. PIERCE,
HON. RALPH K. WINTER,
HON. OSCAR H. DAVIS*,

Circuit Judges,

ORDER

85-6166

FRANK E. BUSH, INC.,

Plaintiff-Appellant,

-v-

UNITED STATES POSTAL SERVICE,

Defendant-Appellee.

This cause came on to be heard on appeal from the United States District Court for the Southern District of New York (Sand, J.), after referral to Magistrate Washington, granting the appellee's motion for summary judgment and denying appellant's motion for a preliminary injunction enjoining enforcement of a mail stop order.

ON CONSIDERATION WHEREOF, it is hereby adjudged, ordered and decreed that the order of the district court be and it hereby is AFFIRMED.

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* United States Circuit Judge for the Federal Circuit, sitting by designation.

1. Appellant argues that a misallocation of the burden of proof tainted the entire administrative proceeding. This claim is without merit. Both the Administrative Law Judge (ALJ) and the Postal Service Judicial Officer properly required the government to bear the initial burden of proof to support its claim of false representation; thereafter the burden shifted to the appellant to come forward with affirmative evidence of truthfulness. See *Texas Dep't. of Community Affairs v. Burdine*, 450 U.S. 248 (1981).

2. Appellant argues that the United States Postal Service (USPS) decision is not supported by substantial evidence. This claim is wholly without merit. The applicable standard is whether there is "substantial evidence" on the record, *N.L.R.B. v. Grease Co.*, 567 F.2d 531, 533 (2d Cir. 1977); *N. Van Dyne Advertising v. USPS*, 371 F.Supp. 1373, 1375-76 (S.D.N.Y. 1974), that the advertisements as a whole would make a false impression on those to whom they were directed. *Donaldson v. Reed Magazine*, 333 U.S. 178, 185-86 (1948). Bush's contentions, inter alia, that it never claimed that NSP-270 would restore sexual functioning and that its claims regarding zinc reflect sound scientific knowledge, simply are in conflict with the government's substantial evidence to the contrary.

3. Appellant argues that the USPS's reliance on material not in evidence requires that its determination be set aside. We disagree. First, even without the material at issue, a government study entitled HANES-2, the government adduced substantial evidence to support the USPS determination. Second, Dr. Sandstead, a government witness, testified as to the findings of HANES-2. Thus, even if the USPS's use of HANES-2 itself was improper, such use constituted mere harmless error.

4. Appellant argues that the postal stop order infringes on its First Amendment rights. This claim is meritless since appellant's advertisements and appurtenant mail correspondence constitute commercial misrepresentations not entitled to First Amendment protections. *Virginia State Bd. of Pharmacy v. Virginia Citizen's Consumer Council*, 425 U.S. 748, 771-72 (1976); *Bristol Meyers v. FTC*, 738 F.2d 554, 562 (2d Cir. 1984), cert. denied, 105 S.Ct.

960 (1985). Further, the form of the stop order is constitutionally sound. *United States Postal Service v. Athena Products*, 654 F.2d 362, 368 (5th Cir. 1981), cert. denied, 456 U.S. 915 (1982).

Affirmed.

HON. LAWRENCE W. PIERCE,

HON. RALPH K. WINTER,

HON. OSCAR H. DAVIS,

Circuit Judges.

N.B. Since this statement does not constitute a formal opinion of this court and is not uniformly available to all parties, it shall not be reported, cited or otherwise used in unrelated cases before this or any other court.

Issued as Mandate: November 22, 1985

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

84 Civ 8756 LBS

FRANK E. BUSH, INC.,

Plaintiff,

– against –

THE UNITED STATES POSTAL SERVICE,

Defendant.

JUDGMENT

Plaintiff having moved for a preliminary injunction and the defendant having moved for summary judgment and the said motions having come before the Honorable Leonard B. Sand, U.S.D.J., and the Court thereafter on May 29, 1985, having handed down its memorandum endorsement denying plaintiff's motion and granting defendant's motion, it is,

ORDERED, ADJUDGED AND DECREED: That the complaint be and it is hereby dismissed.

/s/ Raymond F. Burghardt
Clerk

DATED: NEW YORK, N.Y.
May 31, 1985

MEMORANDUM ENDORSEMENT

FRANK E. BUSH, INC., Plaintiff —against— THE UNITED STATES POSTAL SERVICE, Defendant.

84 CIV 8756 (LBS)

A review of Plaintiff's objections to the Magistrate's Report and Recommendation, the Defendant's response, and a *de novo* review of the relevant portions of the administrative proceedings satisfies us that the objections are without merit and that the Report and Recommendation should be adopted and approved.

The issue is not whether the Defendant and its expert witnesses "maintain a conservative and traditional view of the physiological benefits of zinc." Plaintiff's Objections, p.1. The issues are whether "substantial evidence" supports the ALJ's conclusion that Plaintiff was engaged in a fraudulent scheme in violation of 39 U.S.C. § 3005 and whether, in reaching this determination, proper legal standards and procedures were followed. We answer both questions in the affirmative.

Despite Plaintiff's skillful extraction of phrases out of context and a rewording of contentions, no issues are presented before this Court which have not been fully presented to the Acting Judicial Officer and the Magistrate. No valid basis exists for the claim that the record discloses a misallocation of the burden of proof (see Tr. 1026); there was no improper reliance on a document not in evidence* and no First Amendment rights of the Plaintiff have been infringed.

The First Amendment does not proscribe issuance of a stop order against one who seeks, for example, to portray as relevant to the sexual performance of *otherwise healthy males* distorted results of studies conducted upon Egyptian dwarves, end-stage kidney disease sufferers and a man afflicted with Crohn's disease.

* Plaintiff complains that HANES-2 was improperly utilized as a basis for a critical finding. HANES-2 is not a document. It is an acronym for Health and Nutrition Examination Survey-II, a survey to assess zinc levels in humans, in which Defendant's witness, Dr. Sandstead, participated and as to which he testified.

The Plaintiff's motion for a preliminary injunction is denied and the Defendant's motion for summary judgment is granted.

SO ORDERED.

Dated: New York, N.Y.
May 29, 1985

/s/ Leonard B. Sand
U.S.D.J.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

84 Civ 8756 LBS

FRANK E. BUSH, INC.,

Plaintiff,

– against –

U.S. POSTAL SERVICE,

Defendant.

REPORT AND RECOMMENDATION

TO THE HONORABLE LEONARD B. SAND, U.S.D.J.:

By Order of the Honorable Leonard B. Sand, this matter was referred to the undersigned for a Report and Recommendation on plaintiff's application for a preliminary injunction to enjoin enforcement of a mail stop order issued by the United States Postal Service pursuant to 39 U.S.C. section 3005, and on defendant's motion for summary judgment to dismiss the complaint.

ADMINISTRATIVE HISTORY

On December 22, 1982, defendant United States Postal ("USPS") filed an administrative complaint charging plaintiff Frank E. Bush with being "engaged in a scheme to obtain money through the mails by means of false representation in violation of 39 U.S.C. section 3005" in regard to advertisements relating to plaintiff's product NSP-270. The administrative complaint also requested that a mail stop order be issued pursuant to 39 U.S.C. section 3005(a) (1) and (2).

NSP-270, the product at issue, is in essence a multi-vitamin/mineral preparation sold in tablet form. In addition to other vitamins and minerals, NSP-270 contains 15 milligrams of zinc in its regular strength size; 20 milligrams in its extra strength formulation. The action concerns the role of zinc, and the efficacy of NSP-270, as a sex nutrient.

The administrative complaint alleged that plaintiff falsely represented that:

> (a) U.S. Government research has recently discovered that the average man is significantly deficient in a 'sex nutrient' critical for maximum sexual performance;
>
> (b) Otherside healthy males who are low in the 'sex nutrient' critical for maximum sexual performance will be materially aided in their sexual abilities by ingesting NSP-270;
>
> (c) The efficacy of NSP-270 in improving sexual performance in men has been established by competent scientific tests and studies;
>
> (d) The ingestion of NSP-270 will improve the sexual performance of any man who is low in the 'sex nutrient';
>
> (e) Deficiencies in the 'sex nutrient' serious enough to cause a substantial diminution in sexual performance by males are relatively common in the United States;
>
> (f) A man with a deficiency in the 'sex nutrient' serious enough to cause a substantial diminution in his sexual abilities may otherwise be in good health;
>
> (g) The amount of the 'sex nutrient' contained in NSP-270 is adequate to reverse a deficiency in this nutrient serious enough to cause diminished sexual performance in males;

(h) A. U.S. Navy medical research unit successfully conducted a 'penis enlargement and erection improvement program' using the 'sex nutrient' contained in NSP-270;

(i) Tests conducted by the USDA at Beltsville, Maryland on its own employees revealed that 2 out of 3 were significantly short of the recommended levels of the 'sex nutrient' contained in NSP-270;

(j) The graph set forth in Respondents' advertising material represents actual increases in penis size that may be achieved through the use of NSP-270;

(k) The efficacy of NSP-270 has been established by experiments conducted by the Veterans Administration in Washington, D.C.

An administrative hearing was held before USPS Administrative Law Judge Edwin S. Bernstein from February 28, 1983 through March 2, 1983. Four medical experts testified at the hearing: Dr. Harold H. Sandstead and Dr. James C. Smith, Jr. for the USPS; Dr. Loretta M. McQuillan and Dr. Kasja Suljaga-Petchel for plaintiff. To enable plaintiff to take further testimony from Dr. Sandstead, the record remained open until April 5, 1983 at which time Dr. Sandstead testified at a post-hearing deposition.

ALJ Bernstein issued an Initial Decision on January 25, 1984, and found that plaintiff was engaged in a fraudulent scheme in violation of 39 U.S.C. section 3005. ALJ Bernstein recommended that a mail stop order be issued (Tr. 819-848).

Plaintiff's exceptions to the ALJ's decision were denied in a decision issued by the Acting Judicial Officer on October 10, 1984 (Tr. 1014-33). In addition to sustaining the ALJ's findings, the Acting Judicial Officer issued a mail stop order "forbidding the delivery of mail and the payment of money orders" to plaintiff. The order directed the postmaster at plaintiff's Postal Service stations to return all mail relating to NSP-270 addressed to plaintiff, with the exception of refund requests, stamped: "Return To Sender: Order Issued Against Addressee for Violation of False Representation Law" (Tr. 1034).

Subsequently, in exchange for plaintiff's agreement not to seek a temporary restraining order against enforcement of the mail stop order, the Postal Service agreed not to return the mail in issue to senders until the pending proceeding is decided. Plaintiff's mail, however, is still being detained (Tr. 1035-36).

The present action to review the Postal Service administrative ruling was filed on December 6, 1984.

DISCUSSION

In order to provide injunctive relief the Second Circuit requires "a showing of (a) irreparable harm and (b) either (1) likelihood of success on the merits or (2) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly towards the party requesting the preliminary relief." *Jackson Dairy, Inc. v. H.P. Hood & Sons*, 596 F.2d 70, 72 (2d Cir. 1979); *Bell & Howell: Mamiya v. Masel Supply Co.*, 718 F.2d 42, 45 (2d Cir. 1983).

Ordinarily, therefore, either a likelihood of success on the merits or sufficiently serious questions to make a fair ground for litigation must be shown. But where "Congress authorizes or mandates governmental action that is in the public interest, more than a 'fair ground for litigation' must be shown before the action will be stopped in its tracks by court order." *Union Carbide Agricultural Products, Co. v. Costle*, 632 F.2d 1014, 1018 (2d Cir. 1980), *cert. denied* 450 U.S. 996 (1981).

The Postal Service complaint was filed pursuant to 39 U.S.C. section 3005 and charged plaintiff with conducting a "scheme or device for obtaining money or property through the mail by means of false representations." As the Supreme Court has stated, "[t]he purpose of mail fraud orders is . . . prevention of future injury to the public by denying the use of the mails to aid a fraudulent scheme." *Donaldson v. Read Magazine, Inc.*, 333 U.S. 178, 184 (1948); *see Gottlieb v. Schaffer*, 141 F. Supp. 7 (S.D.N.Y. 1956). Thus, to enjoin an administrative mail stop order the more stringent "likelihood of success" standard is applicable.

Inasmuch as the parties have agreed that mail relating to NSP-270 will not be returned to customers during this proceeding's pendency, plaintiff cannot show that alleged irreparable harm is "actual and imminent." *State of New York v. Nuclear Regulatory Commission*, 550 F.2d 745 (2d Cir. 1977). Plaintiff's reputation and goodwill is not presently being adversely affected.

Though plaintiff's business suffers even though the mail is not being returned to customers, "where an injunction is asked which will adversely affect a public interest for whose impairment, even temporarily, an injunction bond cannot compensate, the court may in the public interest withhold relief until a final determination of the rights of the parties, though the postponement may be burdensome to the plaintiff." *Yakus v. United States*, 321 U.S. 414, 440-41 (1944); *Medical Society of New York v. Toia*, 560 F.2d 535 (2d Cir. 1977); *Brown & Williamson Tobacco Corp. v. Engman*, 527 F.2d 1115 (2d Cir. 1975).

The purpose of a mail stop order is "the prevention of future injury to the public." *Gottlieb v. Schaffer*, 141 F.Supp. 7, 15 (S.D.N.Y. 1956). The granting of injunctive relief would permit plaintiff to incur upon the public the future injury that a presumptively proper mail stop order seeks to prevent. *See Hall v. Willcox*, 225 F. 333 (S.D.N.Y. 1906).

Plaintiff's claim of irreparable harm to his First Amendment rights also must fail. As the Supreme Court stated in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976), "[t]here are commonsense differences between speech that does 'no more than propose a commercial transaction' . . . and other varieties . . . . [A] different degree of protection is necessary to insure that the flow of truthful and legitimate commercial information is unimpaired." *Id.* at 771-72, n.24. Thus, commercial speech is afforded only limited protection, "commensurate with its subordinate position in the scale of First Amendment values . . . ." *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978).

It is noted that the mail stop order at issue was intended to stop what the Postal Service determined to be fraudulent advertisements, and not to regulate the sexual content of plaintiff's advertisements. *Lynch v. Blount*, 330 F.Supp. 689 (S.D.N.Y. 1971), *aff'd* 404 U.S. 1007 (1972).

Summary judgment procedure is particularly appropriate in actions to enjoin or enforce an administrative order, since "where the plaintiff has no right to a trail *de novo*, but is limited to a review of the record before the agency and this record is before the court, the case is ripe for summary disposition, for whether the order is supported by substantial evidence, under the applicable statutory standard, or is otherwise legally assailable, involves matters of law." 6 Part 2 J. Moore & J. Wicker, Moore's Federal Practice, paragraph 56.17[3] at 693-94 (2d ed. 1976); *B & M Coal Corp. v. Office of Surface Mining Reclamation and Enforcement*, 531 F. Supp. 677 (SD Ind. 1982); *Manufacturing Chemists Ass'n v. Costle*, 455 F.Supp. 968 (WD La. 1978).*

Judicial review of a Postal Service determination is a limited one, governed by the "substantial evidence" standard. *See* 5 U.S.C. section 706. "The power so vested in the Postal Service may not be interfered with by the courts unless it has exceeded its authority or is palpably wrong." *N. Van Dyne Advertising Agency, Inc. v. United States Postal Service*, 371 F.Supp. 1373, 1375 (S.D.N.Y. 1974). Thus, "even though the court, as the original trier of fact, might have reached a different conclusion, it may not substitute its own judgment if there is substantial evidence to support the findings of fact . . . ." *Vibra Brush Corp. v. Schaffer*, 152 F.Supp. 461, 463-4 (S.D.N.Y. 1957), *vacated on other grounds*, 256 F.2d 681 (2d Cir. 1958).

Judicial review is a two-step process. First, the court must determine whether there is substantial evidence to support the conclusion that the representations alleged in the administrative complaint were indeed made. If substantial evidence supports the aforementioned conclusion, the court must then determine whether there exists substantial evidence as to the representations' falsity. *Unique Ideas, Inc. v. United States Postal Service*, 416 F. Supp. 1142 (S.D.N.Y. 1976).

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* It is noted that a certified copy of the administrative record, including the administrative hearing transcript and the ALJ's and Acting Judicial Officer's decisions, was submitted to and considered by this Court in conjunction with plaintiff's application for injunctive relief and defendant's motion for summary judgment.

The ALJ ruled, with this ruling affirmed by the Acting Judicial Officer, that the representations alleged to have been made by the administrative complaint were in fact made. This finding is supported by substantial evidence.

Plaintiff contends that it did not represent that the average man is "significantly deficient" in zinc (the nutrient base of NSP-270), since the advertisements only used the terminology "low" or "lower" where addressing the alleged deficiency. The ALJ found, however, that "in the context of other dramatic language surrounding these words" the world "low" conveyed the impression of "significantly deficient" (Tr. 822).

Plaintiff further contends that it did not represent that zinc deficiencies sufficient to cause a substantial diminution in male sexual performance are common in the United States, and points to advertisement language that describes such a sexual nutrition deficiency as "rare." The ALJ ruled that the advertisements' "other language refutes such an impression" (Tr. 826).

As to the aforementioned contentions, however, plaintiff fails to realize that "[i]t is not each separate word or clause here or there of an advertisement which determines its force, but the totality of its contents and the impression of the entire advertisement upon the general populace." *Vibra Brush Corp. v. Schaffer*, 152 F. Supp. 461, 465 (S.D.N.Y. 1957), *vacated on other grounds*, 256 F.2d 681 (2d Cir. 1958). While plaintiff may wish to engage in semantics, fraudulent advertisements are not to be viewed "with a lawyer's eye." *American Image Corp. v. United States Postal Service*, 370 F. Supp. 964, 966 (S.D.N.Y. 1974).

On the issue of whether certain representations were actually made, plaintiff also takes issue as to whether a bar graph used in plaintiff's advertisements "represents actual increases in penis size." (Complainant's Ex. 1, p.3). The careful reader may be able to ascertain from the graph that it is the effect of daily Extra Strength NSP-270 that is being measured in milligrams, and not anatomical enlargement. We are not all careful readers, however, and anatomical enlargement is surely the implied message of the advertisement for one not blessed with a discerning eye. The implication is clear, and "[q]uestions of fraud may be determined

in the light of the effect advertisements would most probabl produce on ordinary minds." *Donaldson v. Read Magazine, Inc.* 333 U.S. 178, 189 (1948). *See N. Van Dyne Advertising Agency Inc. v. United States Postal Service*, 371 F. Supp. 1373, 137 (quoting *Vibra Brush Corp. v. Schaffer*, 152 F. Supp. 461, 465 *vacated on other grounds*, 256 F.2d 681 (2d Cir. 1958)).

The ALJ's determination as to the representations' materia falsity also is supported by substantial evidence.

Plaintiff contends that the Postal Service "conceded" two points that zinc is a critical element for sexual development and abilities and that the average human ingests less zinc than the Recom mended Dietary Allowance (RDA) of 15 milligrams (Tr. 1020) These two concessions, according to plaintiff, act to disestablis the material falsity of the representations made.

However, Dr. Harold Sandstead, one of the Postal Service' medical witnesses and an expert in the specialization of trac minerals – especially zinc – in human nutrition, testified that a average American diet provides 7 to 8 milligrams of zinc daily and that this intake is sufficient to maintain homeostatis. He con cluded that the fact that the average man consumes less zinc tha the RDA requirement does not translate into such a person be ing zinc deficient. To the contrary, Dr. Sandstead was of the belie that the likelihood of impaired sexual function resulting from zinc deficiency was extremely rare. Thus, the fact that the averag person's daily intake of zinc is conceded to be less than the RD requirement and that zinc is a critical nutrient, does not establis the veracity of plaintiff's representations concerning zinc defi ciency and the efficacy of NSP-270 on the male sexual functio (Tr. 22, 23, 29, 31, 1021).

Both of defendant's medical experts, Dr. Sandstead and Dr James Cecil Smith, Jr., are acknowledged experts in the specializa tion of zinc and human nutrition. Plaintiff's medical experts wer a neurological consultant and an epidemiologist, respectively (Tr 580, 582). The ALJ found defendant's medical experts "more im pressive and persuasive" than plaintiff's experts, noting that defen dant's experts "were at the forefront of research and personal in volvement regarding zinc," and that plaintiff's "witnesses, whil

qualified medical doctors, had no personal involvement with zinc and, in essence, read and analyzed research reports of others" (Tr. 831). An ALJ's credibility findings are entitled to special deference. *Moore v. Ross*, 687 F.2d 604 (2d Cir. 1982), *cert. denied*, 459 U.S. 1115 (1983).

Plaintiff also challenges the ALJ's finding of material falsity as to representations concerning two studies involving zinc. As to plaintiff's representation that "a U.S. Naval Medical Research Unit conducted a 'penis enlargement and erection program,' " Dr. Sandstead testified that the study had been concerned with dwarfism, and that the failure of sexual maturation was merely a manifestation thereof (Tr. 44). Furthermore, he testified that the study's emphasis was neither genitalia enlargement nor sexual function. Dr. Sandstead was personally involved in this study, and the "actual experience" of a witness can be considered in determining the probative value of his opinion. *See Hughes v. Hemingway Transport, Inc.*, 539 F. Supp. 130 (E.D. Pa 1982).

As to plaintiff's representation concerning tests conducted by the USDA on its own employees revealing that 2 of 3 were significantly short of the recommended level of zinc, the ALJ found, after examining the context in which the representation was made, that the implication of the representation was that the subjects of the study were sexually deficient, and that this was materially false (Tr. 837-38). The context in which the representation was made was correctly examined, for it "is no defense that specific isolated portions of the advertisements might have been true." *Borg-Johnson Electronics, Inc. v. Christenberry*, 169 F. Supp. 746, 750-51 (S.D.N.Y. 1959).

In light of the testimony of defendant's experts, and the implications that can reasonably be read into plaintiff's representations, there exists substantial evidence to support a finding of material falsity. A Court will not substitute its own judgment for that of an ALJ where supported by substantial evidence. *Vibra Brush Corp., supra*, at 463-4.

Plaintiff also raises some procedural questions concerning the administrative hearing which will now be addressed.

Plaintiff claims that it was required to assume the burden of proving the representations at issue. As the Acting Judicial Officer stated (Tr. 1027, 1032), however:

> Complainant [USPS] established through its expert witnesses that the informed medical and scientific consensus is that the representations set forth in the complaint are false (Tr. 52, 139). By establishing that this consensus exists, Complainant [USPS] made a *prima facie* case as to the falsity of these representations. The burden of going forward with evidence thus shifted to Respondents [plaintiff], who were required to show that the consensus does not exist or that the claim of effectiveness is true despite the lack of acceptance by the medical community . . . . Although the Administrative Law Judge placed the burden of going forward on Respondents [plaintiff], he did not shift the burden of proof. . . .

The ALJ merely shifted the burden of going forward, not the burden of proof. Plaintiff's claimed misallocations of burden, when read in context, are failures to rebut and not failures to prove.

Plaintiff selectively reads *Texas Dept. of Community Affairs v. Burdine*, 450 U.S. 248 (1981), and states that pursuant thereto plaintiff's only burden of going forward was to raise "a genuine issue of fact" and not to specifically rebut each contention. While the Court in *Burdine* does state that "it is sufficient if the defendant's evidence raises a genuine issue of fact," the Court continues by stating that "the explanation provided must be legally sufficient to justify a judgment for the defendant." *Id.* at 254.

Plaintiff's conclusory statement that it did, "at a minimum, show that there is no medical or scientific consensus supporting the USPS' claims of material falsity" (Plaintiff's Memorandum in Support at 14) is insufficient. The Postal Service found otherwise and the power vested therein "may not be interfered with by the courts unless it has exceeded its authority or is palpably wrong." *N. Van Dyne Advertising Agency, Inc. v. United States Postal Service*, 371 F. Supp. 1373, 1375 (S.D.N.Y. 1974).

As to plaintiff's claims of error regarding the 'HANES-2' survey, which was not admitted in evidence, the ALJ did state that the study "showed that over 90 percent of the population have serum zinc levels above 81 micrograms per deciliter" (Tr. 845). It is apparent, however, that the ALJ was relying on Dr. Sandstead's testimony and on Exhibit #17 which refers to HANES-2 data, in reaching his conclusion that over 90 percent of population did not suffer zinc deficiency (Tr. 100-102, 109, 510).

The ALJ referred to HANES-2 a second time, stating that "among recently discovered data is the fact that the overwhelming majority of the population were found to have serum zinc levels sufficiently high to virtually guarantee that they are not deficient notwithstanding the fact that their intake levels are well below the RDA—typically in the range of 8 to 12 mg. per day (HANES-2)" (Tr. 839-40). While the HANES-2 data in Exhibit #17 does not appear to provide information concerning a typical range, Dr. Sandstead testified that in the usual American diet 7 to 8 milligrams of zinc intake is adequate to maintain homeostatis and that the average intake in the United States is 10 to 12 milligrams per day (Tr. 21, 23). Since Dr. Sandstead was testifying as to Exhibit #17 while stating the typical range levels, the ALJ inserted 'HANES-2' as a parenthetical. The Court therefore concludes that the ALJ in fact was not relying on a document not in evidence for his determination.

Finally, plaintiff's contention as to the ALJ's verbatim copying of extensive sections of the defendant's brief requiring reversal must fail. It must be presumed since there is no evidence to the contrary, that the ALJ adopted these findings and conclusions of law after full consideration of the issues, "and they must stand or fall depending on whether they are supported by the evidence." *United States v. Crescent Amusement Co.*, 323 U.S. 173, 185 (1944); *Southern Pacific Communications Co. v. American Telephone & Telegraph Co.*, 740 F.2d 980 (D.C. Cir. 1984).

RECOMMENDATION

Therefore, based on the foregoing, and in light of the entire administrative record and the evidence presented at the administrative hearing, it is the conclusion of the undersigned that plaintiff's application for injunctive relief should be denied and defendant's motion for summary judgment granted.

Pursuant to 28 U.S.C. section 636(b) (1), the parties have ten (10) days in which to lodge written objections to the foregoing report to the Honorable Leonard B. Sand. Such objections should be filed with the Clerk of the Court with extra copies to be delivered to the Chambers of Judge Sand, Room 615, and to the Chambers of the undersigned, Room 121.

Dated: New York, New York
May 15, 1985

Respectfully submitted,

/s/ _____
RUTH V. WASHINGTON

United States Magistrate

Copies of the foregoing Report and Recommendation have been mailed this date to the following:

Anne C. Vladeck, Esq.
Vladeck Waldman Elias & Engelhard, P.C.
1501 Broadway
Suite 800
New York, NY 10036

Richard Mark, Esq.
Assistant U.S. Attorney
One St. Andrew's Plaza
New York, NY 10007

ORDER NO. 84-93 DATE: October 10, 1984

TO THE POSTMASTER AT EAST ROCKAWAY, NY 11518-9998; HEWLETT, NY 11557-9998; ROCKVILLE CENTRE, NY 11571-9998

Satisfactory evidence has been presented to the Postal Service in the case identified below by docket number that

Walter Head
Frank E. Bush, Inc.
P.O. Box 361
East Rockaway, NY 11518-0361

P.O. Box 121
Hewlett, NY 11557-0121

P.O. Box 549
Rockville Centre, NY 11571-0549

P.O. Box 538
Rockville Centre, NY 11571-0538

P.O. Box 362
East Rockaway, NY 11518-0362

and

and their agents and representatives (hereinafter the "Respondent") are engaged in conducting a scheme or device for obtaining money or property through the mails by means of false representations in violation of 39 U.S. Code 3005 (formerly 39 U.S.C. 4005) with respect to the sale of NSP-270.

Now, therefore, pursuant to authority vested in the United States Postal Service, and by it delegated to me, I hereby forbid your payment of any Postal Money Order drawn to the order of the Respondent unless you are satisfied that such order does not relate to the above described activities. Further, you are directed to inform the remitter of any Postal Money Order, the payment of which is forbidden by this Order, that the amount thereof will be refunded upon presentation to you of the original order or a duplicate thereof issued by the Postal Service.

You are further directed to hold for not less than 48 hours (exclusive of days during which your office is not open to the public) all mail addressed to the Respondent, whether registered or not, except for any mail, which you determine, by reference to the face of its wrapper, is unrelated to the above described activities. During the 48 hour retention period Respondent shall be permitted to examine the retained mail in your presence or the presence of a postal employee designated by you and to receive any mail which (1) is not connected with the above described activities, or (2) is mail requesting a refund or representing a return of merchandise connected with such activities.

Following such examination by Respondent or the passage of 48 hours, you are directed to write plainly or stamp the words "*Return To Sender: Order Issued Against Addressee For Violation of False Representation Law*" upon the outside of all mail which the Respondent was not permitted to receive and to return such mail to the post offices from which it was mailed for return to the senders. If the outside of the mail fails to contain information necessary to permit return to the sender, the mail shall be disposed of under the postal regulations applicable to undeliverable matter.

PS Docket No. 15/123; G.C. 285-82-F

/s/ Carroll C. Dicus, Jr.
Acting Judicial Officer

UNITED STATES POSTAL SERVICE
JUDICIAL OFFICER

In the Matter of the Complaint Against October 10, 1984

WALTER HEAD
FRANK E. BUSH, INC.
P.O. Box 361
East Rockaway, NY 11518-0361

and at
P.O. Box 362
East Rockaway, NY 11518-0362

and at
P.O. Box 121
Hewlett, NY 11557-0121

and at
P.O. Box 538
Rockville Centre, NY 11571-0538

and at
P.O. Box 549
Rockville Centre, NY 11571-0549 P.S. Docket No. 15/123

APPEARANCE FOR COMPLAINANT:

Thomas A. Ziebarth, Esq.
Consumer Protection Division
Law Department
United States Postal Service
Washington, DC 20260-1112

APPEARANCE FOR RESPONDENT:

Anne C. Vladeck, Esq.
Vladeck, Waldman, Elias & Engelhard, P.C.
1501 Broadway, Suite 800
New York, NY 10036-5560

POSTAL SERVICE DECISION

Respondent has appealed from the Initial Decision of an Administrative Law Judge which holds that Respondent is engaged in conducting a scheme or device to obtain money through the mail by means of materially false representations in violation of 39 U.S.C. §3005.

Background

On December 22, 1982, the Consumer Protection Division, Law Department, United States Postal Service (Complainant), filed a Complaint alleging that Respondent, by means of materially false direct mail circulars and advertisements, expressly or impliedly represents to the public, directly or indirectly, in substance and effect, whether by affirmative statements, omissions or implications, that:

"3. . . .

(a) U.S. Governmen' research has recently discovered that the average man is significantly deficient in a 'sex nutrient' critical for maximum sexual performance;

(b) Otherwise healthy males who are low in the 'sex nutrient' critical for maximum sexual performance will be materially aided in their sexual abilities by ingesting NSP-270;

(c) The efficacy of NSP-270 in improving sexual performance in men has been established by competent scientific tests and studies;

(d) The ingestion of NSP-270 will improve the sexual performance of any man who is low in the 'sex nutrient';

(e) Deficiencies in the 'sex nutrient' serious enough to cause a substantial diminution in sexual performance by males are relatively common in the United States;

(f) A man with a deficiency in the 'sex nutrient' serious enough to cause a substantial diminution in his sexual abilities may otherwise be in good health;

(g) The amount of the 'sex nutrient' contained in NSP-270 is adequate to reverse a deficiency in this nutrient serious enough to cause diminished sexual performance in males;

(h) A U.S. Navy medical research unit successfully conducted a 'penis enlargement and erection improvement program' using the 'sex nutrient' contained in NSP-270;

(i) Tests conducted by the USDA at Beltsville, Maryland on its own employees revealed that 2 out of 3 were significantly short of the recommended levels of the 'sex nutrient' contained in NSP-270;

(j) The graph set forth in Respondent's advertising material represents actual increases in penis size that may be achieved through the use of NSP-270;

(k) The efficacy of NSP-270 has been established by experiments conducted by the Veterans Administration in Washington, DC".

Two additional false representations alleged in subparagraphs (l) and (m) of Paragraph 3 of the Complaint were dismissed pursuant to Complainant's motion. In a timely filed Answer, Respondent admitted making the representations alleged in subparagraphs (h) and (i) and denied the allegations set forth in subparagraphs (a)-(g) and (j)-(k). A hearing was held before an Administrative Law Judge at which both parties presented documentary and testimonial evidence. Harold H. Sandstead, M.D., and James Cecil Smith, Jr., Ph.D, testified for Complainant; Loretta M. McQuillan, M.Sc., M.D., and Kasja M. Suljaga-Petchel, M.D., testified for the Respondent. Following the hearing, Respondent took Dr. Sandstead's deposition, which was subsequently admitted into evidence. In addition, Dr. Sandstead's "Affirmation" with attached data from the Health and Nutrition Examination Survey II ("HANES-2") was admitted into evidence.

Following the hearing and the parties' submission of proposed findings of fact and conclusions of law and reply briefs, the Administrative Law Judge issued an Initial Decision in which he found that Respondent makes the representations alleged in the Complaint and that they are materially false in violation of 39 U.S.C. §3005. On the basis of these findings, the Administrative Law Judge recommended the issuance of a False Representation Order against Respondent.

Following the issuance of the Initial Decision, Complainant filed a motion to amend the Complaint to include two additional

addresses in the caption. Since Respondent did not interpose any objection, Complainant's motion was granted and the caption now includes the additional addresses of the Respondent.

Respondent's Exceptions to the Initial Decision

In its appeal Respondent presents ten exceptions to the findings and conclusions of the Initial Decision. Each exception is hereafter addressed.

Exception 1

> *"1. The Administrative Law Judge erred in finding that Respondent's advertisement made the representations alleged in paragraphs 3 (a), (b), (c), (d), (e), (f), (g), and (j) of the Complaint."*

Whether Respondent's advertisements make the representations alleged in the Complaint must be ". . . determined in the light of the effect [the advertisements] . . . would probably produce on ordinary minds." *Donaldson v. Read Magazine, Inc.* 333 U. S. 178, 189 (1948); *Peak Laboratories, Inc. v. United States Postal Service,* 556 F.2d 1387, 1389-90 (5th Cir. 1977). In this regard, both the advertisement's express and implied representations must be considered. *N. Van Dyne Advertising Agency, Inc. v. United States Postal Service,* 371 F. Supp. 1373 (S.D.N.Y. 1974); *Vibra-Brush Corp. v. Schaffer,* 152 F. Supp. 461 (S.D.N.Y. 1957), *rev'd on other grounds,* 256 F.2d 681 (2d Cir. 1958). The Administrative Law Judge properly applied the above standards when he found that Respondent made the representations alleged in Paragraphs 3(a)-(k) of the Complaint. The portions of Respondent's advertisements quoted in the Initial Decision (I.D. at 3-12), when read in context, fully support the finding that the alleged representations are made.

Since Respondent failed to specify any reasons why the representations set forth in Paragraphs 3(b), (d), (f), and (g) were not made, no further discussion of those subparagraphs is necessary. Respondent's arguments concerning the remaining contested representations are addressed below under the quoted subparagraphs of Paragraph 3 of the Complaint.

"(a) U.S. Government research has recently discovered that the average man is significantly deficient in a 'sex nutrient' critical for maximum sexual performance."

Respondent first argues that it does not represent that the average man is "significantly deficient" in the nutrient (zinc) because the advertisements merely state that average men are "low" in this nutrient. This argument is rejected. The advertisements state that average males are "surprisingly low" in the nutrient and "lower than they should be" (CX 1-3), which indicates to the ordinary reader that the deficiency is significant.

"(c) The efficacy of NSP-270 in improving sexual performance in men has been established by competent scientific tests and studies."

Respondent argues that no representation is made that the product in issue, NSP-270, has been proven efficacious by competent scientific tests. Respondent maintains that it merely makes this representation with respect to the "sex nutrient" contained in NSP-270, but not the product itself. This argument is rejected. Respondent's advertisements (CX 1 & 2) refer to the product in large lettering occupying about one-third of a page as "a Tested 'Sex Pill' For Men!" Other statements in the advertisements to the effect that the "sex nutrient" found in this product has been studied in scientific tests do not detract from the impression given that NSP-270, itself, has also been tested.

"(e) Deficiencies in the 'sex nutrient' serious enough to cause a substantial diminution in sexual performance by males are relatively common in the United States."

Respondent argues that the advertisements do not represent that these deficiencies are "relatively common." Respondent points to several instances in which the deficiency is described as "rare." However, the Administrative Law Judge correctly found that other language in the advertisements gives the overall impression that the deficiency is relatively common (I.D. at 8). In this regard, the advertisements state in large type that the product is for "average" men. This statement is repeated several times.

"(j) The graph set forth in Respondent's advertising material represents actual increases in penis size that may be achieved through the use of NSP-270."

Respondent argues that the graph does not measure increase in penis size, but merely demonstrates the amount of zinc that individuals with varying levels of zinc deficiency would receive by ingesting one NSP-270 tablet. Although a sophisticated reader might come to this conclusion after a careful analysis of the graph, a person of ordinary mind would interpret the graph as representing increases in penis size that may be achieved through the use of NSP-270. In this regard, the headline on pages 2 and 3 of the advertisement (CX 1, 2) announces in large, bold type a "Revolutionary Medical Discovery For Better Erections!" The advertisement then states "See For Yourself What Extra Strength NSP-270 Can Do!" A vertical bar graph then portrays a series of erections which increase in size depending on the amount of zinc deficiency. The ordinary reader would receive the overall impression as set forth in subparagraph (j). *Donaldson v. Read Magazine, Inc.*, 333 U. S. 178, 189 (1948). Moreover, even if the graph is ambiguous in this regard, it is still misleading. *Rhodes Pharmacal Co. v. F.T.C.*, 208 F.2d 387 (7th Cir. 1953). Respondent's exception has no merit.

Respondent admitted in its Answer that it made the representations set forth in subparagraphs (h) and (i). Also, Respondent did not take exception to the finding that the representation set forth in subparagraph (k) was made. Accordingly, it is concluded that the Administrative Law Judge properly found that the representations were made as alleged in subparagraphs (a) through (k) of Paragraph 3 of the Complaint.

Exception 2

"2. The Administrative Law Judge erred in finding that all of the alleged representations are materially false."

Respondent's arguments concerning the truth or falsity of the representations are addressed following each of the subparagraphs quoted below from Paragraph 3 of the Complaint.

"(a) U.S. Government research has recently discovered that the average man is significantly deficient in a 'sex nutrient' critical for maximum sexual performance.

. . .

(e) Deficiencies in the 'sex nutrient' serious enough to cause a substantial diminution in sexual performance by males are relatively common in the United States."

In an effort to prove the truth of these representations, Respondent relies on two facts which are essentially undisputed. First, Respondent points to the fact that it has been established by scientific studies that zinc is a critical nutrient for sexual development and abilities. Second, the average human ingests less zinc than the Recommended Dietary Allowance (RDA) of 15 mg. per day advocated by the National Academy of Sciences. However, these facts do not establish the truth of the representations in question.

In finding these representations to be false, the Administrative Law Judge relied on the testimony of the Complainant's expert witnesses whom he found "more impressive and persuasive" than Respondent's witnesses. As found by the Administrative Law Judge (I.D. at 20-21), Complainant established through the testimony of Dr. Sandstead that the usual American diet provides 7 to 8 mg. of zinc daily and that this amount is adequate to maintain homeostasis (Tr. 21-22). He also testified that the fact that the average man consumes less zinc than the RDA of 15 mg. per day does not mean that he is deficient in zinc. He noted that there is nothing in the medical literature which would indicate that the average man has such a deficiency (Tr. 34). He characterized the likelihood of impaired male sexual function due to zinc deficiency as "rare as hen's teeth" (Sandstead Deposition [Sandstead Depo.] at 50).

Dr. Sandstead also based his conclusions, in part, on some raw data that he had obtained from the Health and Nutrition Examination Survey-II (HANES-2) conducted by the Department of Health, Education, and Welfare. HANES-2 is the largest survey

that has been conducted to assess zinc levels in humans (Sandstead Depo. at 9). At the time of the hearing, Dr. Sandstead was a member of the group of scientists who were interpreting the raw data of HANES-2 (*Id.* at 21, 45). After Respondent objected to Dr. Sandstead's testimony regarding HANES-2, Dr. Sandstead submitted an "Affirmation" after the hearing and attached the raw data relating to zinc obtained by the survey. These were admitted into evidence. He also testified by deposition that there is little possibility of zinc deficiency unless the level of zinc in the blood is below 70 micrograms per deciliter (*Id.* at 23, 42-43). According to Dr. Sandstead and the HANES-2 data, only about five to ten percent of the population have serum zinc levels below that level (*Id.* at 42-44). These findings demonstrate the falsity of Respondent's representations that the average man is deficient in zinc.

In addition to the above, Complainant introduced the testimony of Dr. Smith to the effect that the RDA for zinc is too high and that the National Academy of Science is considering whether it should be lowered. He predicted that it would be (Tr. 133, 149-50). Respondent complains that the Administrative Law Judge should not have relied on this "prediction" in making his findings. This contention is also rejected. This evidence is merely additional support for the finding of falsity which is fully supported by other evidence of record.

Finally, Respondent attacks the credibility of Dr. Sandstead. Respondent contends that a prior written statement made by Dr. Sandstead is inconsistent with his testimony at the hearing. He previously stated in a published article that "[c]urrent data suggest that mild zinc deficiency is not a rare phenomenon" (RX 12 at 117). He testified at the hearing that zinc deficiency in the United States is "probably more widespread than most people preach" (Tr. 56). However, these statements are not necessarily inconsistent with Dr. Sandstead's other testimony. Regarding the publication, the context of the statement included other countries and addressed diseases affecting zinc absorption. Moreover, the fact that something is "not rare" does not mean that it is common. As to his comment during cross-examination it is not known what "most people preach," so the statement by itself does not

indicate an incidence of zinc deficiency in conflict with his other testimony. In any event, Dr. Sandstead's testimony at the hearing was based significantly on the HANES-2 data, which clearly demonstrates that the average man is not deficient in zinc.

Respondent also contends that another statement, made by Dr. Sandstead in a 1982 article, is inconsistent with his reliance on the plasma zinc data from HANES-2 in this proceeding. He had previously stated:

> At present, there is no single, unequivocal index for measurement of zinc status of humans. Plasma zinc represents the most readily available and easily analyzed zinc pool. However, under circumstances of deficiency, plasma zinc may not reliably reflect depletion. A finding of low plasma zinc is presumptive evidence of impaired zinc nutriture, if a redistribution of zinc caused by an acute stimulus can be ruled out. On the other hand, normal plasma levels may be found even though the patient is zinc depleted. [footnotes omitted]. (RX 12 at 101)

The above statement is not inconsistent with Dr. Sandstead's testimony in the instant case. In reaching his conclusion that zinc deficiency is not widespread (Sandstead Depo., at 44), he relied in part on plasma zinc levels in the population obtained from HANES-2. However, he admitted:

> . . . having a plasma zinc of 70 or 72 in and of itself does not diagnose zinc deficiency. There is a lot more to it than simply a blood level. You can't prove that somebody is deficient on the basis of that. (*Id.* at 42).

His use of the HANES-2 plasma zinc data as reliable "presumptive evidence" for the purpose of proving that the *average* man is not deficient in zinc is not inconsistent with his previous statement.

Respondent also disputes the credibility of Dr. Sandstead in light of his statement at trial characterizing Respondent's advertising as a "gross, sleazy fraud" (Tr. 41). He made that comment while describing the portion of the advertisement concerning the

"Tennessee man."

He first testified that it was a "fraud" for Respondent to have stated that the man's penis began to grow "almost immediately" after taking zinc. Dr. Sandstead noted that he himself had treated this man with zinc for an entire year and that he had showed "small changes." It was only after quadrupling the amount of zinc and removing part of his small bowel that he subsequently began to mature over a 6-month period. While Dr. Sandstead's characterization of this and other misrepresentations as a "gross, sleazy fraud" may have been intemperate, the Administrative Law Judge had an opportunity to observe the demeanor of Dr. Sandstead and determined he was a credible witness. Respondent has failed to give any valid reason why the determination by the Administrative Law Judge should not be sustained.

> *"(b) Otherwise healthy males who are low in the 'sex nutrient' critical for maximum sexual performance will be materially aided in their sexual abilities by ingesting NSP-270."*
>
> . . .
>
> *"(f) A man with a deficiency in the 'sex nutrient' serious enough to cause a substantial diminution in his sex abilities may otherwise be in good health."*

The Administrative Law Judge found these representations false on the ground that a person with a zinc deficiency severe enough to diminish sexual abilities would not be "otherwise healthy" (I.D. at 25-26). This finding was fully supported by the testimony of Complainant's experts. They established that impairment of sexual abilities due to zinc deficiency would be accompanied by other problems such as dermatitis, impaired night vision, and loss of taste acuity (Tr. 161; Sandstead Depo. at 49). It was also established that impairment of sexual abilities would usually be accompanied by such illnesses as malnutrition, intestinal malabsorption, renal failure, alcoholism, and cirrhosis (Tr. 31-34, 126-27).

There is no credible evidence of record that rebuts the above testimony by Complainant's experts. The studies Respondent relies on do not involve impairment of "sexual abilities" as that term is used in Respondent's advertisements. The latter define "weak sexual abilities" as "poor erections . . . low sex drives . . . inability to satisfy a woman in bed" (CX 1, 2 at 2). In contrast, various studies in the record address zinc as a treatment for subjects suffering dwarfism, renal malfunction and Crohn's Disease. Even the studies indicating that zinc deficiency causes a reduction in sperm count and testosterone levels (RX 6-8) do not address impaired sexual functioning. Therefore, these studies do not tend to prove the truth of Respondent's representations with respect to impairment of "sexual abilities" as defined by the advertisements.

In addition to improving "sexual ability," the advertisement also claims that NSP-270 will restore "reproductive functioning." It is noted that the zinc deficiency was artificially induced by dietary means in one of the studies relied on by Respondent, and it does not appear that the authors attempted to measure any effects of zinc deficiency other than gonadal function (RX 6, 7). Also, the Netter study (RX 8) found that oral administration of zinc increased the testosterone and sperm count levels of infertile males. However, these patients were given about four times the amount of zinc contained in Respondent's tablets, and the authors characterized their findings as "preliminary data."

Accordingly, Respondent's exception to these findings has no merit.

> *"(b) The ingestion of NSP-270 will improve the sexual performance of any man who is low in the 'sex nutrient'.*
>
> . . .
>
> *(g) The amount of the 'sex nutrient' contained in NSP-270 is adequate to reverse a deficiency in this nutrient serious enough to cause diminished sexual performance in males."*

NSP-270 tablets contain either 15 or 20 milligrams of zinc. The Administrative Law Judge found that the ingestion of 15 or 20 mg. of zinc has not been shown to improve sexual function (I.D. at 27-28). This finding is based on the testimony of Dr. Sandstead who has been an expert in zinc nutrition for about 20 years (Tr. 21, 34). He also testified that there is no evidence that the ingestion of zinc, in any amount, would improve the sexual performance of a person who does not manifest any of the other symptoms of zinc deficiency (Tr. 34-35). Complainant established that Dr. Sandstead's views are consistent with the informed medical and scientific consensus (Tr. 52). By establishing that this consensus exists, Complainant made a *prima facie* case as to the falsity of the above representations. The burden of going forward with evidence thus shifted to Respondent, who was required to show either that the consensus does not exist or that the claims are true despite the lack of acceptance by the medical community. *Cosvetic Labs., et al.*, P. S. Dockets Nos. 8/160 and cases consolidated therewith (P.S.D. July 22, 1982, at 14); *Standard Research Laboratories*, P. S. Docket No. 7/48 (P.S.D. April 4, 1980) and cases cited therein; *cf., Texas Dept. of Community Affairs v. Burdine*, 450 U. S. 248 (1981).

Respondent's evidence is not persuasive to prove that the scientific and medical consensus is in error. Respondent points to Dr. Sandstead's own study with dwarfed, sexually retarded adolescent boys in Egypt (CX 13) to prove that small amounts of zinc can reverse a zinc deficiency. However, the patients in that study were extreme cases. Moreover, they were treated with one and a half to two times the amount of zinc contained in Respondent's product. This evidence fails to rebut the informed consensus.

> *"(c) The efficacy of NSP-270 in improving sexual performance in men has been established by competent, scientific tests and studies.*
>
> . . .
>
> *(k) The efficacy of NSP-270 has been established by experiments conducted by the Veterans Administration in Washington, D.C."*

Since Respondent admits that NSP-270, itself, has never been tested, the above representations are false. Moreover, as indicated in the discussion of subparagraphs (b) and (g), above, no competent, scientific tests and studies have been performed which prove that 15 or 20 mg. of zinc, the amount contained in NSP-270, improves sexual performance in males (Tr. 34).

In addition, the study performed at the Veterans Administration Hospital in Washington, DC. (CX 19) fails to prove the efficacy of Respondent's product. The study indicated that zinc deficiency is a major, reversible cause of impotence in some hemodialysed men. However, the zinc deficiency resulted from renal failure, so the implications of the test results are severely limited. In addition, substantially larger amounts of zinc were administered to these patients than the amount contained in Respondent's product. Further, although these patients took 100 to 150 mg. of oral zinc a day during the initial stages of the study, oral administration was discontinued because it raised plasma-zinc levels only slightly over a period of six months. Thereafter, the zinc was added directly to the dialysis bath. Although the latter means of administration appeared to be successful, this study fails to prove the efficacy of oral zinc products such as NSP-270.

Finally, the Administrative Law Judge found that the conclusion of the VA study was cast in doubt by a subsequent study (I.D. at 23; CX 25; Tr. 152-54), and noted Dr. Smith's testimony that the question is "still up in the air." Thus the Administrative Law Judge found representation (k) to be false, in part, because the conclusions of the VA study cannot properly be characterized as scientifically "established" in view of the later, contrary study. The finding of falsity is supported by this rationale. However, falsity is more clearly demonstrated by the fact that the VA study fails to establish the efficacy of NSP-270 since the latter contains much less zinc and is administered orally.

> *"(h) A U. S. Naval Medical Research Unit successfully conducted a 'penis enlargement and erection improvement program' using the 'sex nutrient' contained in NSP-270."*

The record fully supports the finding of falsity made by the Administrative Law Judge with respect to this representation. Respondent's advertisements make it appear that the primary goal of the U. S. Naval Medical Research Unit was "penis enlargement and erection improvement." However, growth of the male genitalia was only one aspect of the study and "erection improvement" was not even considered. In contrast to the impression created by Respondent's advertisements, the study made a wide variety of clinical and biochemical findings on a group of economically deprived Egyptian adolescents with growth retardation and associated zinc deficiency (CX 13).

> *"(i) Tests conducted by the USDA at Beltsville, MD on its own employees revealed that two out of three were significantly short of the recommended levels of the 'sex nutrient' contained in NSP-270."*

As found by the Administrative Law Judge, Respondent's advertisements give the impression that the USDA study found that two out of three subjects had a significant zinc deficiency. This representation is false. The USDA study merely found that two-thirds of the subjects consumed less than the RDA for zinc in their self-selected diets. As discussed previously with respect to subparagraphs (a) and (e), the fact that the average man consumes less than the RDA for zinc does not mean that he has a zinc deficiency. Moreover, even if the advertisement is susceptible of two meanings, it is still ambiguous. *Rhodes Pharmacal Co. v. F.T.C., supra.* Accordingly, this exception has no merit.

> *"(j) The graph set forth in Respondent's advertising material represents actual increases in penis size that may be achieved through the use of NSP-270."*

As previously indicated, the Administrative Law Judge properly held that a person of ordinary mind would have read the graph in Respondent's advertisements as set forth in subparagraph (j). The "before and after" pictures contained in the graph indicate that a man who takes NSP-270 will triple the size of his penis. Respondent does not seriously contend that the product will actually increase penis size as indicated on the graph, but simply argues that the graph does not make the alleged representation.

Dr. Sandstead testified that NSP-270 would not cause enlargement of the type indicated on the graph (Tr. 49) and there is no persausive evidence of record that NSP-270 would result in enlargement of the magnitude depicted in the graph. Accordingly, the finding of falsity by the Administrative Law Judge is sustained.

Exceptions 3 - 9

> *"3. The Administrative Law Judge erred by wholesale rejection of expert medical testimony which supports Respondent's representations.*
>
> . . .
>
> *4. The Administrative Law Judge erred in crediting Complainant's witness' at-trial statements that were inconsistent with the witness' prior statements which supported Respondents."*

In making his findings regarding the truth or falsity of the representations, the Administrative Law Judge set forth the qualifications and experience of all expert witnesses who testified in this proceeding (I.D. at 13, 16). He found Complainant's witnesses to be "more impressive and persuasive" than Respondent's witnesses. He also found that Complainant's witnesses were at "the forefront of research and personal involvement regarding zinc." On the other hand, he found that Respondent's witnesses did not have any special expertise in the field of nutrition and their testimony was primarily based on their review of the published literature on zinc nutrition (I.D. at 13, 16).

The record fully supports the conclusion by the Administrative Law Judge that the testimony of Complainant's witnesses was more reliable in view of their superior qualifications. Under the circumstances, it was appropriate for the Administrative Law Judge to rely on this testimony in making his findings of fact. Accordingly, Exception 3 has no merit.

In Exception 4 Respondent attacks the credibility of Complainant's expert witnesses by alleging that prior inconsistent statements were made. Since no material inconsistencies have been found, Exception 4 has no merit. These alleged inconsistencies have been previously discussed, to the extent necessary, under Exception 2 with regard to subparagraphs (a) and (e).

> *"5. The Administrative Law Judge erred in adopting virtually verbatim, Complainant's post-hearing submissions without a full and independent review of the record as a whole.*
>
> . . .
>
> *6. The Administrative Law Judge erred in relying on a publication not in evidence."*

Respondent contends that the Administrative Law Judge failed to examine all of the evidence of record. In support of this position he points to the fact that the Administrative Law Judge adopted verbatim many of the proposed findings of fact submitted by Complainant. Then Respondent notes that the citation to "HANES-2" in the Initial Decision (I.D. at 22, 28) demonstrates that he failed to examine the record "since the HANES survey was not in evidence." However, it is clear that the Administrative Law Judge was not relying on any document not in evidence, but was merely relying on the data from HANES-2, which was attached as an exhibit to Dr. Sandstead's "Affirmation" dated March 21, 1983, and subsequently made a part of the record by order of the Administrative Law Judge dated May 2, 1983. Therefore, it was appropriate for the Administrative Law Judge to rely on this data in making his findings of fact, and his citation to that data does not indicate a failure to review the evidence of record.

In addition, all of the evidence of record has been carefully reviewed on appeal and it is concluded that the findings of the Administrative Law Judge are supported by a preponderance of the evidence. Accordingly, these exceptions have no merit.

"7. The Administrative Law Judge erred by shifting the burden of proof to Respondent to prove efficacy rather than properly placing it on Complainant to prove falsity."

As previously indicated, Complainant established through its expert witnesses that the informed medical and scientific consensus is that the representations set forth in the Complaint are false (Tr. 52, 139). By establishing that this consensus exists, Complainant made a *prima facie* case as to the falsity of these representations. The burden of going forward with evidence thus shifted to Respondents, who were required to show either that the consensus does not exist or that the claim of effectiveness is true despite the lack of acceptance by the medical community. *Cosvetic Labs., et al., supra.* Although the Administrative Law Judge placed the burden of going forward on Respondents, he did not shift the burden of proof. Therefore, this exception has no merit.

"8. The Administrative Law Judge erred in finding that lack of medical consensus, or issues 'still up in the air,' support a finding of falsity."

Respondent argues, in effect, that there is consensus that zinc is necessary to male sexual development and that the consensus is not affected by the inconclusiveness of certain tests. While it is not in dispute that zinc is an essential nutrient affecting sexual development, Respondent's advertisement makes representations about "maximum sexual performance" and organ growth in average American men. As Dr. Sandstead testified, impaired sexual functioning in American males due to zinc deficiency is essentially non-existent (Sandstead Depo. at 50). Thus, while the zinc in Respondent's product can reverse some zinc deficiencies, it has not been shown that small organ size or poor sexual performance in American males is attributable to zinc deficiency. As to the specific test at a Veterans Hospital which Respondent cites, zinc was not administered orally and the dose was much larger than contained in NSP-270. *See* Exception 2(k). Not only was the test inconclusive, as the Administrative Law Judge found,

but the nature of the patients (men with severe renal failure on dialysis) and the method and quantity of zinc administered render the test ineffective as support for Respondent's position. Respondent's exception is without merit.

> *"9. The Administrative Law Judge erred in relying on a non-medical doctor's 'prediction' which is totally contrary to all the evidence of record."*

This issue was previously addressed under Exception 2 in the discussion of subparagraphs (a) and (e). For the reasons previously stated, this exception has no merit.

Exception 10

"10. The Administrative Law Judge erred in finding that a False Representation Order should be issued."

As addressed throughout this decision, the record amply supports the Administrative Law Judge's conclusion that a False Representation Order should be issued.

CONCLUSION

After consideration of the entire record and Respondent's exceptions to the Initial Decision, it is concluded that Respondent is engaged in a scheme to obtain money through the mail by means of materially false representations. Accordingly, Respondent's appeal is denied and a remedial order under 39 U.S.C. §3005 is issued herewith.

Carroll C. Dicus, Jr.

Acting Judicial Officer

UNITED STATES POSTAL SERVICE
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of the Complaint Against January 27, 1984

WALTER HEAD
FRANK E. BUSH, INC.
P.O. Box 361
at
East Rockaway, NY 11518-0361

Post Office Box 362
at
East Rockaway, NY 11518-0362

Post Office Box 0121
at
Hewlett, NY 11557-0121 P.S. Docket No. 15/123

APPEARANCE FOR COMPLAINANT:

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Consumer Protection Division
Law Department
United States Postal Service
Washington, DC 20260-1100

APPEARANCE FOR RESPONDENT:

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1501 Broadway
New York, NY 10036-5560

BEFORE:

Judge Edwin S. Bernstein

INITIAL DECISION

Complainant alleged and Respondent denied that Respondent was engaged in conducting a scheme or device for obtaining money or property through the mails by means of false representations in violation of 39 United States Code §3005. By Order

dated February 25, 1983, Complainant's unopposed motion to add Paragraph 4 to the Complaint was granted and by Order dated June 2, 1983, Complainant's unopposed motion to dismiss subparagraphs 3(l) and 3(m) of the Complaint was granted. At the hearing, Dr. Harold H. Sandstead and Dr. James C. Smith, Jr., testified for Complainant while Dr. Loretta M. McQuillan and Dr. Kasja Suljaga-Petchel testified for Respondent. Dr. Sandstead also testified by post-hearing deposition. The parties filed proposed findings of fact, proposed conclusions of law and memoranda. These have been considered. To the extent indicated, they have been adopted. Otherwise, they have been rejected as irrelevant or not supported by the evidence.

Findings of Fact

I. *The Use of the Mails*

Respondent's advertising materials solicit remittances of money through the mail in connection with the sale of Respondent's product NSP-270. In its Answer, Respondent admits an allegation to this effect which was made in Paragraph 1 of the Complaint. Additionally, Respondent's advertising materials (CX-1, 2 and 3) substantiate the allegation. A copy of CX-1 is attached as Exhibit 1 to this Decision.

II. *The Advertising Representations*

I further find that Respondent's advertisements make all the representations alleged in Paragraph 3 of the Complaint which are listed below, based upon the following language in Respondent's advertisements and rationale.

> *(a) U. S. Government Research has recently discovered that the average man is significantly deficient in a "sex nutrient" critical for maximum sexual performance.*
>
> New Medical Discovery! U. S. Government Research Team Finds Average Men Low in Nutrient Critical For Maximum Sexual Performance!
>
> (CX-1 & 2, p. 1, CX-3)

Latest Findings Show Many *Average* Men Are Lower Than They Should Be!

. . . .

In Denver, Colorado, an accidental discovery suddenly rocked the medical world back on its heels. Surprisingly low sex nutrient levels were discovered in "average"males who, up until then, had been thought to be normal. (Even though their girlfriends had always known they were "short"!)

(CX-1 & 2, p. 2, CX-3)

U. S. Government
Research Team
Finds Average
Men Low In
Nutrient Critical
For Sex!

(CX-1 & 2, p. 7, CX-3)

At page 12 of its proposed findings, Respondent argues that it does not expressly represent that the average man is "significantly deficient" in zinc and the use of the words "low" and "lower" in advertisements should not be interpreted to mean "significantly deficient". While "low" and "lower" by themselves can mean less than "significantly deficient", in the context of other dramatic language surrounding these words, I find that the advertisements' language impliedly represents that the average man is "significantly deficient" in zinc, the sex nutrient referred to in this matter. Such language, which includes "New Medical Discovery", "rocked the medical world back on its heels", "surprisingly low sex nutrient levels", conveys the impression that "low" means significantly low or significantly deficient.

(b) Otherwise healthy males who are low in the "sex nutrient" critical for maximum sexual performance will be materially aided in their sexual abilities by ingesting NSP-270.

If your level is low in the micro nutrient critical for maximum sexual performance, NSP-270 is guaranteed to help you get it up . . . and keep it up . . . to where experts say it should be! Yes, now – if you are in good health otherwise – and your sexual problems are a result of this rare deficiency – you can be sure that your erection is getting a FULL CHARGE of this vital sex nutrient, so it will always be "up to the mark" for maximum sexual performance!

(CX-1 & 2, p. 1, CX-3)

Cure For Weak Sexual Powers Discovered!

(CX-1 & 2, p. 2, CX-3)

See For Yourself What Extra Strength NSP-270 Can Do!

Perks Up The Sex Lives of World War II Vets!

(CX-1 & 2, p. 3, CX-3)

Revolutionary Medical Disvocery for Better Erections!

(CX-1 & 2, pp. 2-3)

(c) The efficacy of NSP-270 in improving sexual performance in men has been established by competent scientific tests and studies.

Now!
A Tested
"Sex Pill"
For Men!

(CX-1 & 2, p. 1)

New Findings from medical research! Doctors have discovered that, in amazing but true cases, weak sexual ability—poor erections . . . low sex drive . . . inability to satisfy a woman in bed—can stem from a very rare sexual nutrition deficiency that has been treated in almost every case through the use of an amazing "sex nutrient" found in NSP-270!

(CX-1 & 2, p. 2, CX-3)

NOW! A GUARANTEED "SEX PILL" FOR MEN!

(CX-3)

Cure for Weak Sexual Powers Discovered!

The first breakthrough came in animal research at leading universities. Scientists traced weak sexual ability and reproductive failures to a micro mineral deficiency—then cured that deficiency and restored normal, healthy sex drive . . . erections . . . and reproductive functioning . . . using the amazing sex nutrient found in NSP-270!

(CX-1 & 2, p. 2, CX-3)

Because, in our files, we have actual proof and medical photographs that show

- Dramatic new erection power!
- New ability to satisfy a woman in bed!
- Amazing spurts of penis growth!
- Sensational ejaculations!

. . . all thanks to the use of the amazing sex nutrient in NSP-270! ACT NOW!

(CX-1 & 2, p. 4, CX-3)

(d) The ingestion of NSP-270 will improve the sexual performance of any man who is low in the "sex nutrient."

Revolutionary Medical
Discovery For Better
Erections!

(CX-1 & 2, pp. 2-3)

NSP—270 is now being released to adult men, for your private and personal use. If your "sex nutrient" level is low, NSP-270 is guaranteed to help you get it up . . . keep it up . . . and keep your organ growing! Yes, if you are in good health otherwise, in this respect we guaranteed that when you have an erection—now your erection will always be "up to the mark" for maximum sexual performance!

Yes, if you want to be sure that your erection has the sex nutrients it needs to do the best job possible . . . if you want to be sure that your sperm is getting what it needs to "keep it perking" . . . if you want to be absolutely certain that your sex life won't "die young" due to sex nutrient depletion . . . NSP-270 is guaranteed to give you the full daily sex nutrient charge—and more—that experts say you need to keep your organ standing "ready and able"!

(CX-1 & 2, p. 4, CX-3)

(e) Deficiencies in the "sex nutrient" serious enough to cause a substantial diminution in sexual performance by males are relatively common in the United States.

U. S. Government
Research Team
Finds Average
Men Low in
Nutrient Critical
For Sex!

Vital Announcement
For Men!

(CX-1 & 2, Envelope)

Latest Findings Show Many
Average Men Are Lower Than
They Should Be!

(CX-1 & 2, p. 2)

Then came the most amazing sex discovery of the century-:

In Denver, Colorado, an accidental discovery suddenly rocked the medical world back on its heels. Surprisingly low sex nutrient levels were discovered in "average" males who, up until then, had been thought to be normal. (Even though their girlfriends had always known they were "short"!)

So important were these findings that the U. S. Department of Agriculture at Beltsville, Maryland, repeated the Colorado research using their own methods. And they encouraged their own employees to take part in this revolutionary program! The result? Two out of three so-called "average" subjects in the program were proven short of the recommended level that has been established by the National Research Council of the National Academy of Sciences. Yet, NSP-270 was all they needed to bring them "up to the mark" . . . and beyond!

(CX-1 & 2, p. 2, CX-3)

Although the advertisements refer to "this rare deficiency", the other language refutes such an impression. Such references as "average men low" in the heading, "if you are in good health otherwise," "average men are lower than they should be", "two out of three so-called 'average' subjects . . . were proven short of the recommended level", effectively contradict the word "rare" and represent that deficiencies in NSP-270's sex nutrient or zinc are relatively common.

(f) A man with a deficiency in the "sex nutrient" serious enough to cause a substantial diminution in his sexual abilities may otherwise be in good health.

> If your "sex nutrient" level is low, NSP-270 is guaranteed to help you get it up . . . keep it up . . . and keep your organ growing! Yes, *if you are in good health otherwise,* in this respect we guarantee that when you have an erection – now your erection will always be "up to the mark" for maximum sexual performance! (underscoring supplied)
>
> (CX-1 & 2, p. 4)

> Now NSP-270 is guaranteed to help keep your daily sex nutrient intake level up to and above where experts say it belongs, so that now, when you have an erection – *if you are in good health otherwise* – and if your sexual problems are a result of this rare deficiency – you can be sure that your erection is getting all the sex nutrient it needs to be "up to the mark" for maximum sexual performance!
>
> (CX-1 & 2, p. 1)

(g) The amount of the "sex nutrient" contained in NSP-270 is adequate to reverse a deficiency in this nutrient serious enough to cause diminished sexual performance in males.

If your level is low in the micro nutrient critical for maximum sexual performance, NSP-270 is guaranteed to help you get it up . . . and keep it up . . . to where experts say it should be! Yes, now – if you are in good health otherwise – and your sexual problems are a result of this rare deficiency – you can be sure that your erection is getting a FULL CHARGE of this vital sex nutrient, so it will always be "up to the mark" for maximum sexual performance!

(CX-1 & 2, p. 1, CX-3)

(h) A U. S. Navy medical research unit successfully conducted a "penis enlargement and erection improvement program" using the "sex nutrient" contained in NSP-270.

This allegation was admitted in Respondent's Answer and is supported by the following language in Respondent's advertising:

> U. S. Navy Uses This Discovery To Give Men Dramatic Increases In Penis Size
>
> Among the official U. S. Government agencies that quickly took an interest in this astonishing sex discovery was the U. S. Navy's Medical Research Unit #3. Boys who couldn't measure up to the Navy's proud standards of manhood . . . who would never be able to satisfy a "woman in every port" . . . who would disgrace the uniform if they were ever allowed to wear it . . . were given massive dosages of this amazing sex nutrient found in NSP-270. And, the results of this U. S. Navy penis enlargement and erection improvement program have been hailed by the medical press throughout the world!
>
> Fellows who were totally impotent . . . who couldn't ejaculate . . . who suffered from embarrassingly small penis dimensions—suddenly and dramatically experience—
>
> - Proud Erections!
> - Dramatic New Ability In Intercourse!
> - Supercharged Sperm That Now Can "Do The Job!"
>
> . . . And, most amazing of all, *fantastic growth in penis size!*
>
> (CX-1 & 2, p. 2, CX-3)

(i) Tests conducted by the USDA at Beltsville, Maryland on its own employees revealed that 2 out of 3 were significantly short of the recommended levels of the "sex nutrient" contained in NSP-270.

This allegation was admitted in Respondent's Answer and is supported by the following language in Respondent's advertising:

> So important were these findings that the U. S. Department of Agriculture at Beltsville, Maryland repeated the Colorado research using their own methods. And they encouraged their own employees to take part in this revolutionary program! The result? Two out of three so-called "average" subjects in the program were proven short of the recommended level that has been established by the National Research Council of the National Academy of Sciences. Yet, NSP-270 was all they needed to bring them "up to the mark" . . . and beyond!
>
> (CX-1 & 2, p. 2, CX-3)

(j) The graph set forth in Respondent's advertising material represents actual increases in penis size that may be achieved through the use of NSP-270.

The graph found on page 3 of Respondent's advertising brochure invites the reader to "See for yourself what extra strength NSP-270 can do!" A series of before and after entries on the graph strongly imply to the average male reader that the ingestion of extra strength NSP-270 will cause a substantial increase in the size of his penis.

(k) The efficacy of NSP-270 has been established by experiments conducted by the Veterans Administration in Washington, D.C.

Perks Up The Sex Lives Of World
War II Vets!

After reviewing the wonderful results that were now being achieved with this amazing sex discovery by medical teams around the world—in England . . . Iran. .New York. .and Tennessee—whose work was giving men, good, healthy erections . . . sperm that could do the job . . . increased sex drive . . . sensational spurts of penis growth—the Veteran's Administration in Washington, DC, began conducting sex nutrient experiments of its own, on older men—haemodialysed World War II vets—who had totally lost their ability to have sex.

The result! In just two weeks, men whose sex lives had been down to rock bottom zero . . . men who couldn't get an erection no matter how hard they tried . . . men whose organs were absolutely limp—suddenly found themselves getting erections with ease!

(CX-1 & 2, p. 3, CX-3)

Here Are Some Of The Actual
Results Doctors Have Achieved
In Part By Using The Amazing "Sex Nutrient"
Found in NSP-270!

* * * *

True Case History #782
Restores The Sexual
Potency Of
Haemodialysised
World War II Vets!

(CX-1 & 2, p. 6)

III. *The Truth or Falsity of The Representations*

Before discussing the truth or falsity of each allegation in Paragraph 3, I make the following preliminary findings:

A. Respondent's Products

NSP-270 is a multi-vitamin-mineral preparation furnished in tablet form. Each tablet contains, among other things, 100% (or more) of the RDA of vitamins A, C, D and E, as well as a number of vitamins in the B complex. Also included are true minerals, iodine, iron and zinc.

NSP-270 comes in two strengths, regular strength (CX-5) and extra strength (CX-5a). The formulations are identical except that regular strength NSP-270 contains 12.5 mg. of B-6 (625% of the RDA) and 15.0 mg. of zinc (100% of the RDA). Extra strength NSP-270 contains 25 mg. of B-6 (1,250% of the RDA) and 20.0 mg. of zinc (133% of the RDA).

All of the evidence in this proceeding relates to the role of zinc as a supposed sex nutrient. The essential difference between regular strength NSP-270 and extra strength NSP-270 is that regular strength NSP-270 provides 100% of the RDA of zinc while extra strength NSP-270 provides 133% of the RDA of zinc.

B. The Witnesses

I found that Complainant's witnesses, Doctors Sandstead and Smith, were more impressive and persuasive than Respondent's witnesses, Doctors McQuillan and Petchel. Complainant's witnesses, were at the forefront of research and personal involvement regarding zinc. Respondent's witnesses, while qualified medical doctors, had no personal involvement with zinc and, in essence, read and analyzed research reports of others.

Dr. Harold H. Sandstead received his medical degree from Vanderbilt University School of Medicine in 1958. His post-graduate work includes an internship and residency at Barnes Hospital in St. Louis, Missouri and a further residency at Vanderbilt University School of Medicine. His academic appointments

include Assistant Professor of Biochemistry and Medicine as well as Associate Professor Nutrition all at Vanderbilt University School of Medicine. He is currently an adjunct professor of Biochemistry and Medicine at the University of North Dakota School of Medicine and is Director of the Nutrition Division of the Department of Internal Medicine at that institution.

Since 1971 Dr. Sandstead has been Director of the Human Nutrition Research Center of the United States Department of Agriculture Research Service at Grand Forks, North Dakota. He is board certified in Internal Medicine as well as in Nutrition. He is on a large number of committees dealing primarily with problems of nutrition, especially those involving trace minerals. He has served or is currently serving on the editorial boards of a number of prestigious medical journals. (CX-10)

Dr. Sandstead's area of specialization is the role of trace minerals – especially zinc – in human nutrition. He has published widely in this field. (CX-10, Tr. 21) There are a total of 19 articles from peer-review medical journals in this record. Dr. Sandstead is the author or co-author of eight of them including two introduced by Respondent. (CX-11-13, 15-17; RX-9, 12) Dr. Sandstead is a recognized leading expert in zinc nutrition. Dr. McQuillan who testified for Respondent, acknowledged that Dr. Sandstead is one of the outstanding researchers in the field. (Tr. 213)

Dr. James Cecil Smith, Jr. is Laboratory Chief of the Vitamin and Mineral Nutrition Laboratory, Nutrition Institute, United States Department of Agriculture, Beltsville, Maryland. He is also a Professional Lecturer in Biochemistry at George Washington University School of Medicine, in Washington, DC. Dr. Smith's research activities are outlined in his Curriculum Vitae. (CX-20) He has over 71 abstracts and 78 articles in the peer-reviewed medical or scientific literature in which he is either the lead author or co-author. (CX-21, 22)

Dr. Smith's particular area of interest and expertise is trace element nutrition, especially zinc. (CX-20, 21, 22; Tr. 113) He is one of the co-authors of CX-19 and CX-26.

Dr. Loretta M. McQuillan received her M. Sc. and M.D. degrees from the University of British Columbia, Vancouver, Canada. She did her internship at the Cooper Hospital, New Jersey, which is affiliated with the University of Pennsylvania. She has done a residency in both Internal Medicine and Neurology at New York Medical College and is specialty board eligible. She is licensed to practice medicine in Canada and New York.

Dr. McQuillan's research activities since receiving her M.D. degree are in the field of Neurology including the use of L-Dopa in the treatment of Parkinson's Disease and studies of chronic brain disease. (RX-2) Her Curriculum Vitae lists no publications. There is nothing to indicate that she has any special expertise in the field of nutrition. Her testimony in this proceeding was based on her review of the published medical literature. (Tr. 183, 186, 190, 213, 229)

Dr. Kasja M. Suljaga-Petchel (hereafter Dr. Petchel) received her medical degree from the University of Zagreb School of Medicine in Yugoslavia. She did post-graduate work in public health at the University of Zagreb and further studies at the Harvard University, School of Public Health where she received her M.Sc. degree in 1976. Her field of specialization is Epidemiology of Noncommunicable Diseases. (RX-3, 5; Tr. 247-9)

Dr. Petchel's published materials are all in the Croatian language (with English abstracts available). She has several additional articles in preparation. (RX-3) She was recently advised that she had been certified by the American Board of Preventive Medicine as a specialist in Public Health and General Preventive Medicine. (RX-4)

Like Dr. McQuillan, Dr. Petchel has no particular expertise in nutrition or trace element nutrients. She relied primarily on the published literature on zinc nutrition in preparing for her testimony. (Tr. 251-253, 265, 272-3, 277-85)

Findings Regarding the Representations

I further find that, except for subparagraphs l and m, the representations set forth in Paragraph 3 of the Complaint are materially false. The representations, but not necessarily in the order alleged, together with the basis of my findings follow:

> *(h) A U. S. Navy medical research unit successfully conducted a "penis enlargement and erection improvement program" using the "sex nutrient" contained in NSP-270.*

Respondent's advertising labels the research program conducted by the U. S. Navy's Medical Research Unit No. 3 as a "penis enlargement and erection improvement program." What the advertisements did not disclose is that the subjects of this research were Egyptian boys suffering from malnutrition so acute that their growth was severely stunted. Moreover, the advertisements implied that the subjects were potential Navy recruits: "Boys who couldn't measure up to the Navy's proud standards of manhood . . . who would never be able to satisfy a woman in every port . . . who would disgrace the uniform if they were ever allowed to wear it." The facts relating to the research activities of the U. S. Navy's Medical Research Unit No. 3 were set forth in Exhibits CX-12, 13 and 14. (Also Tr. 42-48, 95-96)

Dr. Sandstead, who was personally involved in this study, pointed out:

> That work was done on Egyptian adolescent boys. It was not done on U. S. Naval personnel. It was done at the U. S. Naval Medical Research Unit No. 3. The persons involved were on the faculty of Vanderbilt who were working there on a N.I.H. grant. There were some U. S. Naval personnel who participated. August Miale, Jr. was a U. S. Naval medical officer. I was a U. S. Public Health Service officer, at that time. Dr. Prasad was there and Arthur Shulert was there

> as Vanderbilt staff. Dr. Soheir Farid an Egyptian [was] director of clinical investigation of NAMRU. Dr. Bassilly was an Egyptian physician employed to manage the ward on a day-to-day basis. (Tr. 43-44)

Dr. Sandstead emphasized that, it was not a study to measure enlargement of the male genitalia.

* * * *

> We were interested in their dwarfism, growth failure, a severe dwarfism, similar to hypopituitism, a depression of the function of the pituitary gland. There is a dwarfism associated with failure to produce growth hormone. These people had impaired growth. Many of them were iron deficient. One of the manifestations in association with their dwarfism was a failure of sexual maturation. They appeared to have an arrested development. A person of 16 years of age would appear to be 9. (Tr. 44)

Biologically, these young men were actually children and the fact that they may not have had a sex life was "not a part of the issue." (Tr. 45-46) Dr. Sandstead explained,

> That wasn't the reason we were studying them. We studied them because their overall development was arrested. It was a very unusual type of dwarfism. (Tr. 46)

Dr. Sandstead noted that even without therapy, people similar to the subjects eventually matured sexually.

> Prasad also studied some subjects at an oasis in upper Egypt, and I believe that was Kharga Oasis, who had zinc deficiency and growth failure and delayed sexual maturation. They received no therapy at all. They were studied

again several years later, the same subjects by Dr. Yankovel, and over time, they had gradually matured, much later than most people in this country. They had eventually matured. They were small in stature, but had matured sexually. I suspect this is what happens to many of these people in the villages. I might point out that they have lots of children. (Tr. 46)

(i) Tests conducted by the USDA at Beltsville, Maryland on its own employees revealed that 2 out of 3 were significantly short of the recommended levels of the "sex nutrient" contained in NSP-270.

Respondent's advertisement contains a paragraph that states: "Surprisingly low sex nutrient levels were discovered in 'average' males who, up until then, had been thought to be normal." Respondent adds parenthetically, "(Even though their girl friends had always known they were 'short'!)". Immediately following this paragraph Respondent's advertisement refers to the self-selected diet study conducted by the U. S. Department of Agriculture's Nutrient Composition Laboratory at Beltsville, MD. (CX-1, 2, para. 2) The impliction is that the subjects of the Beltsville study were sexually deficient. The Beltsville experiment is described in detail by Holden, *et al.*, in the article, *Zinc and Copper in Self-Selected Diets.* (CX-23) This study found that the subjects' average intake of zinc was 8.6 mg. per day. While this is below the RDA for zinc of 15 mg. per day, there was no indication that any of the subjects manifested symptoms of zinc deficiency. Moreover, this intake level is in line with many of the zinc intake levels reported in the literature. (CX-23, pp. 25-26 and table 5)

Dr. Sandstead testified that the usual American diet provides between 7 and 8 mg. of zinc daily and that this is adequate to maintain homeostasis. (Tr. 21-22)

The record contains evidence that many average people consume less zinc daily than the recommended daily allowances (RDA's) established by the National Academy of Science. (Tr. 53, 57-58, 258-259, CX-23) However, this does not establish that

the average person is significantly deficient in zinc critical for his maximum sexual performance. When the RDA for zinc was first established in 1974 there was very little information available and the 15 mg. level was based on very limited observations. (Tr. 28) That number probably came from the data of a Dr. Spencer who found her subjects in equilibrium at 12.5 mg. A few more milligrams were added empirically. Fifteen seemed like a good number. (Tr. 29)

It is not correct to say that a person getting less than the RDA is deficient. Deficiency is another issue. As Dr. Sandstead noted, "Most of us consume less than the RDA. Obviously, we are not in bad health." (Tr. 29)

Dr. Sandstead testified that he follows all research done in zinc and that this research is massive. He is not aware of any research that would suggest that the average man in the United States is significantly deficient in zinc. (Tr. 30) Very few cases of zinc deficiency are seen in the United States. Dr. Sandstead concluded that since there is no clinical evidence that many people are deficient in zinc, he must assume that they are not deficient. (Tr. 31)

In establishing recommended dietary allowances the National Academy of Science attempts to set the levels high enough to insure that virtually all persons will receive enough of the nutrient to insure against any possibility of deficiency. (Tr. 28)

Since the RDA was established at 15 mg./day there have been important advances in knowledge about the actual requirements for zinc by humans. It now appears that the RDA for zinc as established by the National Academy of Science is excessive. Dr. Smith predicted that the RDA for zinc will be substantially lowered as a result of recently discovered data. Such a change is under consideration by the National Academy of Science. (Tr. 133, 149-50) Among these recently discovered data is the fact that the overwhelming majority of the population of the United States were found to have serum zinc levels sufficiently high to virtually guarantee that they are not deficient notwithstanding the fact that their zinc intake levels are well below the RDA—typically in the range of 8 to 12 mg. per day. (HANES-2)

(j) The graph set forth in Respondent's advertising material represents actual increases in penis size that may be achieved through the use of NSP-270.

Respondent's advertising represents that NSP-270 is effective in increasing the size of the male user's penis. This implication is made in the "before and after" illustrations contained in the bar graph. A similar representation is made in the paragraph headed, "Tennessee Man Doubles the Size of His Penis." This section is meant to imply and does imply that ingestion of NSP-270 will do the same thing for other "average men" who "are lower than they should be." The young man in question was Dr. Sandstead's patient. A detailed account of the case is given in *Zinc Deficiency in Crohn's Disease*. (RX-9) Before treatment the subject had the appearance of a 12 year old child. In some respects his problem was similar to the adolescents in Egypt and Iran in that his growth generally was severely retarded. While the size of his genitalia doubled, this most probably was because he was biologically a child before treatment. The Nashville case was very unusual. The patient suffered from a significant intestinal malabsorption problem. The treatment involved not only surgery to remove part of his small bowel but massive doses of zinc – up to 400 mg./day. This is 26 times the RDA and the equivalent of 20 extra strength NSP-270 tablets! (Tr. 40)

(k) The efficacy of NSP-270 has been established by experiments conducted by the Veterans Administration in Washington, D.C.

An article entitled, *Reversal of Uraemic Impotence by Zinc* (CX-19) describes an experiment conducted at the Veterans Administration Hospital in Washington, D.C. It involved eight men who had been on haemodialysis for a number of years. They all had low plasma-zinc levels and suffered some degree of impotence although *libido* was normal.

Initially the patients were given large doses of zinc orally. (150 mg. per day) Because of gastric disturbances, that was later reduced to 100 mg. per day. This increased their plasma-zinc

levels only slightly over a period of six months. The oral zinc was discontinued and, instead, zinc chloride was added directly to the dialysis bath. This resulted in an increase in plasma-zinc from an average of 63 micrograms/deciliter to a range of 100 to 150 micrograms/deciliter. It was accompanied by a striking improvement in potency. The study concluded that zinc deficiency is a major, reversible cause of impotence in some haemodialysed men.

The findings of the Veterans' Administration Hospital, however, were cast in doubt by an experiment conducted by Brook, *et al* in England. (CX-25) Using essentially the same technique of adding zinc chloride to the dialysis bath, Brook found that the administration of zinc had no significant effect on any aspect of sexual functions whether measured by subjective or objective criteria.

Dr. Smith, one of the co-authors of CX-19 who personally participated in the VA study emphasized that it is by no means established that zinc deficiency is a reversible cause of gonadal dysfunction. While Prasad, another authority on zinc, was of the opinion that oral zinc may have some impact, Brook and his colleagues found no effect. Dr. Smith concluded that question is "still up in the air." (Tr. 152-3)

(a) *U.S. Government Research has recently discovered that the average man is significantly deficient in a "sex nutrient" critical for maximum sexual performance.*

Respondent's advertising refers to four U. S. Government related activities. These are (1) the research of Naval Medical Unit No. 3; (2) the USDA Self-Selected Diet Experiment; (3) the Nashville Case, and (4) the Veterans Administration Study. For the reasons already discussed none of these activities substantiates the representation and there is no other evidence of record of any other U. S. Government research discovery that substantiates the representation.

(b) *Otherwise healthy males who are low in the "sex nutrient" critical for maximum sexual performance will be materially aided in their sexual abilities by ingesting NSP-270.*

(f) *A man with a deficiency in the "sex nutrient" serious enough to cause a substantial diminution in his sexual abilities may otherwise be in good health.*

Although Respondent's advertising repeatedly suggests that a person might be otherwise healthy and still be so deficient in zinc as to impair sexual function, there is nothing in the record to support such a position. On the contrary the "case histories" cited by Respondent all involve persons who were far from "otherwise healthy." The adolescent boys and young men in Egypt and Iran were so malnourished that they suffered a severe dwarfism. (CX-14) The young man in Nashville had Crohn's disease which, in addition to zinc therapy, required numerous hospitalizations and surgical intervention. (RX-9) A person requiring haemodialysis would hardly be called "otherwise healthy." (CX-23, 26)

Dr. Smith testified that persons who have clinically definable features of zinc deficiency would be malnourished in general. If a person had sexual dysfunction as a result of malnutrition, it would be part of a complicated condition. (Tr. 126-27) In any event, if a person had a serious zinc deficiency merely taking the RDA would not reverse the condition. (Tr. 128-29) He pointed out that administering the RDA brought about no improvement in the Iranian subjects. Six to ten times the RDA is required in the dialysis subjects and then it is not even administered orally. (Tr. 130-31)

On cross-examination, Dr. Smith noted that sexual dysfunction is not the first sign of a zinc deficiency. One would first see dermatitis, impaired night vision and other problems. (Tr. 161)

Dr. Sandstead testified that persons with a serious zinc deficiency will suffer from dermatitis. They will usually have some other underlying disease and zinc deficiency is just one of a host of things related to that. Several examples he gave are: intestinal malabsorption, renal failure, alcoholism and cirrhosis. He concluded that then the ingestion of the RDA would not be sufficient to reverse the condition. (Tr. 122)

(c) *The efficacy of NSP-270 in improving sexual performance in men has been established by competent scientific tests and studies.*

The record contains absolutely no evidence that NSP-270 (either regular strength or extra-strength) has been tested in any way. Moreover, there is no evidence of any clinical study or test involving the administration of zinc in doses of 15 or 20 mg. per day.

The record does contain medical articles about the use of zinc therapy in treating various forms of sexual dysfunction. However, these studies involve much larger doses, different modes of administration, and frequently other modes of treatment in which zinc therapy is only a part. There is no reason to conclude that NSP-270 would not have been useful in treating the subjects of the articles in this record. (CX-11-14, RX-9, 12)

Dr. Sandstead testified that he knows of nothing in the literature that would tend to show that the ingestion of the RDA of zinc would improve sexual performance. (Tr. 34) There is no evidence that a zinc supplement taken by a person with no deficiency symptoms would improve his sexual function except, possibly, a placebo effect which, he added, is not a pharmacological phenomenon. (Tr. 35)

(e) *Deficiencies in the "sex nutrient" serious enough to cause a substantial diminution in sexual performance by males are relatively common in the United States.*

The HANES-2 data show that zinc deficiencies are uncommon in the United States. Over 90% of the population have serum zinc levels of 81 or better. Seventy is considered the threshold level at which zinc deficiency might occur and Dr. Sandstead has never seen an individual with a zinc deficiency with a serum zinc level above 60. (Deposition 49) There is no data on the record to contradict these reliable findings.

The HANES-2 survey is a comprehensive study that was undertaken to determine the nutritional status of the American population as a whole. (Tr. 105) The study showed that over 90 percent of the population have serum zinc levels above 81 micrograms per deciliter. (Tr. 109) Moreover, Dr. Sandstead testified, "we don't become suspicious . . . until plasma zinc is less than 70." (Tr. 110) Although Dr. Sandstead did state that "zinc deficiency is probably more widespread than people preach" (Tr. 56), other statements by Dr. Sandstead (Tr. 31, 34, 100) and the HANES-2 data do not support a finding that zinc deficiency is particularly common in the United States.

(d) *The ingestion of NSP-270 will improve the sexual performance of any man who is low in the "sex nutrient".*

(g) *The amount of the "sex nutrient" contained in NSP-270 is adequate to reverse a deficiency in this nutrient serious enough to cause diminished sexual performance in males.*

As indicated by the evidence, although the average American ingests less than the RDA, he is not deficient in zinc. As I have previously found, the ingestion of 15 or 20 mg. of zinc has not been shown to improve sexual function. Sexual function was only improved through zinc in persons suffering from other problems who ingested doses of zinc much larger than found in NSP-270.

CONCLUSIONS OF LAW

1. The meaning of an advertising representation is to be judged from a consideration of the advertisement in its totality and the

impression it would most probably create in ordinary minds. *Donaldson v. Read Magazine,* 333 U. S. 178 (1948); *Vibra-Brush Corp. v. Schaffer,* 152 F. Supp. 461 (S.D.N.Y. 1957); *Borg-Johnson Electronics v. Christenberry,* 169 F. Supp. 746 (S.D. N.Y. 1959).

2. An advertisement as a whole may be completely misleading although every sentence separately considered is literally true. This may be because things are omitted that should be said, or because advertisements are composed or purposefully printed in such a way as to mislead. *Donaldson v. Read Magazine, supra.*

3. The average person reading Respondent's advertisements would interpret them substantially as characterized in Paragraph 3, subparagraphs (a) through (k) of the Complaint.

4. The effect of false representations is not dispelled by a money-back guarantee. *Borg-Johnson Electronics v. Christenberry, supra.*

5. Complainant has established its case by means of reliable, probative and substantial evidence of record. *Leach v. Carlile,* 258 U. S. 138 (1922); *Donaldson v. Read Magazine, supra.*

6. The Postal Service need not show actual victims in a proceeding of this type. See: *Norton v. U. S.,* 92 F.2d 753 (9th Cir. 1937).

7. In the context of Respondent's other advertising language the use of the word "rare" in various phrases does not serve to erase or outweigh the claims represented. A disclaimer will not necessarily refute otherwise emphatic representations. *See: Gottlieb v. Schaffer,* 141 F. Supp. 7 (S.D.N.Y. 1956); *Vibra-Brush v. Schaffer, supra; Black Magic Shop Astral Co.,* P.O.D. No. 2/210 (1965); *Virtu Imports, Inc.,* P.O.D. 3/2 (1968); *Manuel Garcia Imports,* P. S. 5/127 (1977).

8. Therefore Respondent is engaged in the conduct of a scheme for obtaining money through the mails by means of materially false representations in violation of 39 U.S.C. §3005 and a False Representation Order in the form attached should be issued against Respondent.

Edwin S. Bernstein
Administrative Law Judge